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EMC & Product Safety in Medical Devices

Based on 3rd Edition of IEC60601-1.

Presented by Michael Brun
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EMC

Radio

Telecom

Environmental

Product Safety

International Approvals

Agenda

9:30-10:45 - Overview of standard changes in IEC60601 family.

- **“State of the art in safety” for Medical Devices**
- **Review of HAZARD, RISK, NORMAL CONDITION and SINGLE FAULT CONDITION concepts and their impact on compliance**

11:00-12:15 – Zoom-in on EMC requirements.

- **Test mode and essential performance**
- **Documentation requirements**

12:30-13:15 - Lunch

13:30-14:45 - Zoom-in on other critical changes.

- **Home Healthcare**
- **Changes in Technical Requirements**

15:00-16:00- Review of requirements for International market access

- **International market access on example of Japan**

16:00-16:30 - Questions and Answers.

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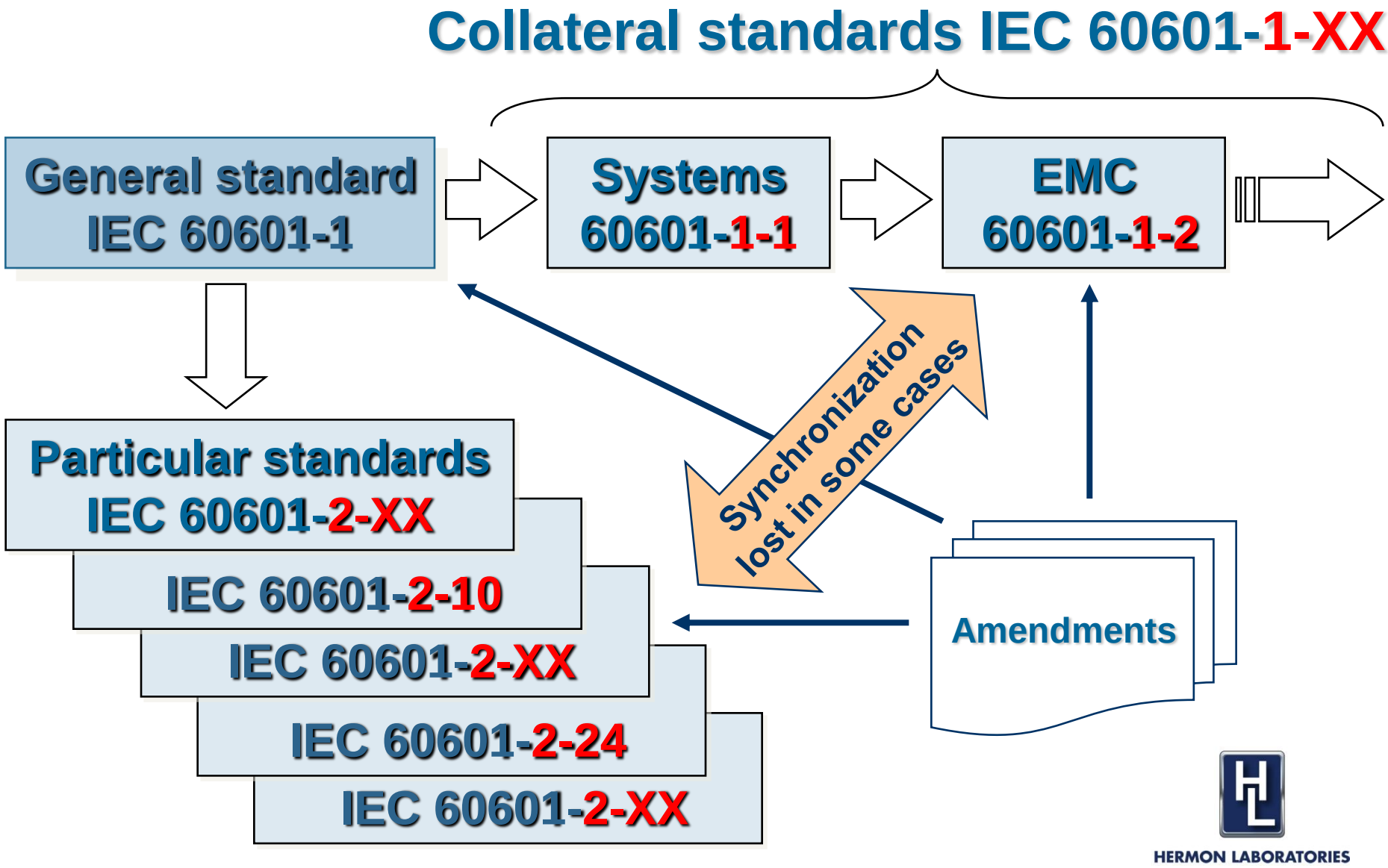
IEC 60601-X-XX Standards structure



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Background

The latest version of IEC 60601-1, its 3rd Edition "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance", was published in 2005.

National standards for IEC 60601-1 3rd Edition were published in Europe, USA and Canada.

Alignment of existing collateral standards IEC 60601-1-XX and most of particular standards IEC 60601-2-XX to 3rd Edition is completed.

All new collateral and particular 60601-X-XX standards are aligned to 3rd Edition.

NOTE: The main standard shall be used together with the collaterals and particulars aligned with this main standard. It may be a position of specific regulatory body to accept 2nd Edition of main standard with particular standard aligned with 3rd Edition.

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EN 60601-1-XX status information

Collateral Standard	Title	Comment
EN 60601-1-1	SAFETY REQUIREMENTS FOR MEDICAL ELECTRICAL SYSTEMS	incorporated (cl. 16)
EN 60601-1-2	ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS	
EN 60601-1-3	GENERAL REQUIREMENTS FOR RADIATION PROTECTION IN DIAGNOSTIC X-RAY EQUIPMENT	
EN 60601-1-4	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS	incorporated (cl. 14)
EN 60601-1-6	USABILITY	
EN 60601-1-8	GENERAL REQUIREMENTS, TESTS AND GUIDANCE FOR ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEMS	
EN 60601-1-9	Requirements for environmentally conscious design	not in OJ
EN 60601-1-10	Requirements for the development of physiologic closed-loop controllers	now!
EN 60601-1-11	Home health care	now!

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IEC 60601-1 3rd Edition: Why NOT to do it now?

Technical:

- **Do not comply with 3rd Edition.**
- **Particular standard exist only for 2rd Edition (e.g. Part 2-24: Particular requirements for the safety of infusion pumps and controllers IEC 60601-2-24:1998).**

Logistics:

- **Many markets still do not accept 3rd Edition**
- **In most cases of particular standards, your product will become "clinical trial" for test methods.**

It has taken time for the industry and regulators to understand the new concepts. Major issue can arise which will take much time to get resolved.

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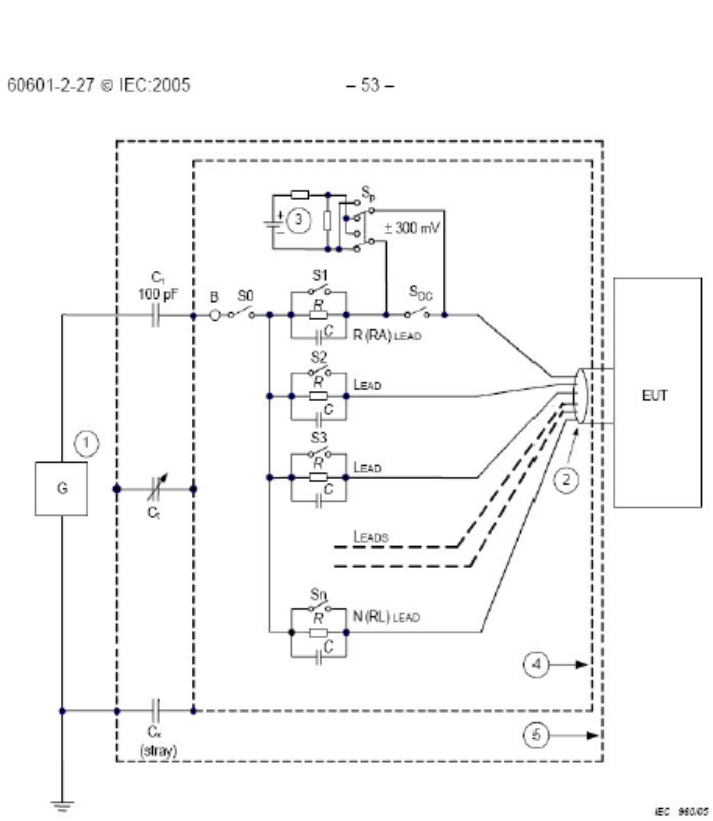
EN 60601-2-27: facilities and test methods

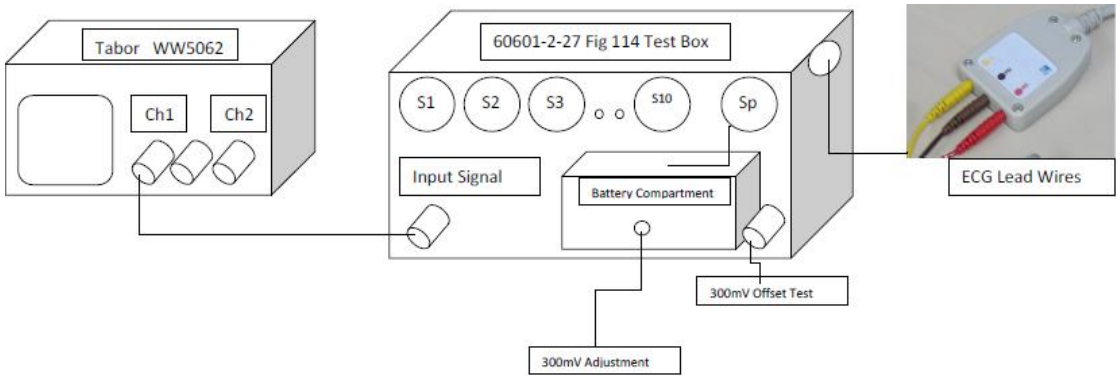


Components

1	Signal generator 20 V_{rms} mains frequency
2	PATIENT CABLE
3	DC offset voltage source
4	Inner shield
5	Outer shield
B	Common mode point
S1-Sn	Switches; including, or provoking shortcut of, unbalance circuit consisting of C and R
C	47 nF
R	51 kΩ

C_1 and C_t simulate the PATIENT's capacitance to ground. The inner shield is used to reduce the pickup of unwanted extraneous signals and to eliminate the unbalance to ground. Since the capacitance C_x between the inner and external shields influences both the source capacitance and the common mode voltage, this capacitance is increased by trimmer capacity to 100 pF, equal to the generator capacitor C_1. The generator output is increased to 20 V_{rms}, thus providing 10 V_{rms} at the common mode point B with a source impedance equivalent to 200 pF when the PATIENT CABLE is not connected to the test circuit.

Figure 114 – Test circuit for common mode rejection
(See 50.102.10)



ANSI-AAMI-EC13-2002 Annex C

Need for this annex

Many questions and vigorous discussions in and outside of committee meetings have arisen over the proper design, construction, and use of the test circuit prescribed in this standard for CMR and channel noise testing. It is the intent of this annex to resolve those questions and discussions, and, in so doing, foster greater testing consistency.

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IEC 60601-1 3rd Edition: Why to do it now?

Technical reasons:

- Product introduction is only expected in 2012
- Product does not comply with 2nd Edition.
- Particular or collateral standards exist only for 3rd Edition, e.g. Home Healthcare products.

http://www.uluniversity.us/Content/73/MediaLibrary/Home_Healthcare_Whitepaper.pdf

Logistics:

- General tendency for complicating existing requirements and adding new ones.
- It may be easier now to get Certificate to 3rd Edition than in 1 year from now.
- Product requires major modification in 2 years from now. It may be more cost effective to make file update.

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Re-Defining term “safety” for MD

Certification agencies traditionally excluded high risk specialized equipment from scope of safety standards.

Good example are products for use in military or aircraft applications.

On other hand, for alarm system US and European standards have included performance requirements as part of “safety” for years. Manufacturers cannot get NRTL Listing without compliance with functional aspects.

In Europe, harmonized functional standards exist. They are not part of CE Mark Directive, but insurances in Europe require compliance.

3rd Edition recycle term “safety” to make sure regulatory practice also cover MD critical performance aspects.

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Basic Safety

2nd Edition: Regulatory > Safety > Quality > Functionality

3rd Edition: Basic Safety and Essential Performance

BASIC SAFETY is freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION.

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ESSENTIAL PERFORMANCE

ESSENTIAL PERFORMANCE (EP) is defined as performance necessary to achieve freedom from unacceptable RISK.

Medical Devices (MD) are integral part of modern medical care.

MD functionality and reliability also associated with quality of care.

The quality of MD has been always part of regulation. Compliance with ISO 13485 is part of regulatory requirements for MD.

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HAZARD-HARM-RISK: what is the difference?

HAZARD is any source of potential damage, harm or adverse health effects on something or someone under certain conditions at work.

HAZARD can cause HARM

- **to individuals as health effects, or**
- **to organizations as property or equipment losses.**

RISK is combination of the probability of occurrence of HARM and the severity of that HARM

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Traditional SAFETY Concepts

2nd Edition: Regulatory > Safety > Quality > Functionality

SAFETY standard is set of requirements for construction and performance of Medical Device (MD) to ensure a sufficient degree of protection against SAFETY HAZARDS under NORMAL CONDITION and SINGLE FAULT CONDITION.

But IEC60601-1-2:2001, 2nd Edition (EMC) already has term EP (taken from draft of IEC60601-1:2005).

It allows a risk analysis to be used to determine the EP and safety of MEDICAL ELECTRICAL EQUIPMENT that must be examined during IMMUNITY testing.

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RISK MATRIX

RISK is combination of the probability of occurrence of HARM and the severity of that HARM

	Severity				
Probability	Catastrophic	Serious	Moderate	Minor	Not relevant
Very Likely	High	High	High	Medium	No Risk
Likely	High	High	Medium	Low	No Risk
Unlikely	Medium	Medium	Low	Negligible	No Risk
Remote	Low	Low	Negligible	Negligible	No Risk
Not relevant	No Risk	No Risk	No Risk	No Risk	No Risk

Risk can be acceptable (e.g. green area) or unacceptable (red).

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Operating Conditions

NORMAL CONDITION: condition in which all means provided for protection against SAFETY HAZARDS are intact.

SINGLE FAULT CONDITION: Condition in which

- **a single means for protection against a SAFETY HAZARD is defective, or**
- **a single external abnormal condition is present.**

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Re-defining terms for Operating Conditions

Faults are divided into 3 probability categories:

- **so remote that they can be ignored (e.g. REINFORCED INSULATION, TENSILE SAFETY FACTOR of 8X, COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS)**
- **probable enough that they need to be considered, but improbable enough that they need only be considered one at a time (SINGLE FAULT)**
- **so likely, so unpredictable or undetectable that they are considered to be a NORMAL CONDITION and need to be considered individually and collectively (“WORST CASE”).**

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WORST CASE or SINGLE FAULT?

Until now, two or more independent faults were considered so unlikely that only “single-fault” issues need be considered

Where the probability of multiple faults is high enough (e.g., due to water spillage, inadequate design for ageing or corrosion), then two or more independent faults could occur with sufficient likelihood and can even be considered “WORST CASE” of NORMAL OPERATION.

General rule is failure of anything less than one MOP (means of protection) is considered NORMAL OPERATION

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MOP

The reliability of components that are used as MOP shall be assessed for the conditions of use in the product. They shall comply with one of the following :

- **the applicable safety requirements of a relevant IEC, ISO or national standard;**
- **where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.**

Example: Gaskets and Seals shall comply to IEC60950-22, National Standards UL50E and UL 157

Testing for IP protection without gaskets if gaskets are not approved.

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Compliance, Standards, and Tolerable Risks

Achieving regulatory approval for a given market does not necessarily guarantee that a product has tolerable safety risks.

Product liability and safety laws exist in all developed countries.

These laws vary in their application in different countries, due to their different legal traditions, and they may vary between different states within the U.S., and even between different counties within a state.

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NFPA99

NFPA99 definition of Wet Location includes all operating rooms. The current practice allows hospital to conduct risk assessment and for those operation rooms that are not wet they do not have to use GFCI or isolated power.

Report on Comments A2009 — Copyright, NFPA

4.3.2.2.8.3* Operating Rooms. Operating rooms shall be considered to be a wet procedure location unless a risk assessment conducted by the health care governing body determines otherwise.

Add a new annex item A4.3.2.2.8.3 to read: In conducting a risk assessment, the health care governing body should consult with all relevant parties including but not limited to clinicians, biomedical engineering staff and facilities safety engineering staff.

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NFPA99 Discussion minutes

99-94 Log #75 HEA-ELS **Final Action: Reject**
(3.3.185 Wet Locations and A.3.3.185)

Submitter: Kim Jahn, Manning Regional Healthcare Center
Comment on Proposal No: 99-68
Recommendation: Delete text to read as follows:

3.3.185* Wet Locations. The area in a patient care area where a procedure is performed that is normally subject to wet conditions, ~~including all operating rooms~~, while patients are present, including standing fluids on the floor or drenching of the work area, either of which condition is intimate to the patient or staff.

A.3.3.185 Wet Locations. Routine housekeeping procedures and incidental spillage of liquids do not define a wet location. ~~Spillage of liquids in an operating room location where surgery is performed is considered a wet location.~~

Substantiation: MRHC has 1 surgery suite and 1 minor procedure room. All electrical receptacles are grounded and we have not had any electrically related incidents in either location since I began employment here in 1985. I believe the proposed changes to the code will only increase my costs of operation in a time when everyone in this country is complaining about the high cost of healthcare. Making this change is totally unjustified in my opinion.

~~including all operating rooms,~~ & ~~Spillage of liquids in an operating room location where surgery is performed is considered a wet location.~~ These deletions were proposed by ASHE, and I agree with them.

Committee Meeting Action: Reject
Committee Statement: See the Committee Action and Statement on Comment 99-89 (Log #64).
Number Eligible to Vote: 23
Ballot Results: Affirmative: 21

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CE: Manufacturer responsibilities

“Member States shall take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in this Directive ...”

A product is “placed on the market” when it is made available for the first time. This is considered to take place when a product is transferred from the stage of manufacture with the intention of distribution or use on the Community market.

“Putting into service" means the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose;

Both terms refer to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series.

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CE: Placement on the market

The product “placed on the market” or “put into service” must meet the current list of harmonized standards as the standards are updated and published under the European Journal.

Once withdrawn, the standard will be removed from the EU list of harmonized standards and will no longer provide a presumption of conformity for the purposes of CE marking.

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Europe: Product Liability Directive

The product should comply with the "state of the art in safety" on the day it was supplied or put into service.

"State of the art" for European product liability means "the state of scientific and technical knowledge" at that time, which includes all published standards, even those not listed under a Directive.

Complying with the regulatory standards for medical equipment and systems does not necessarily ensure compliance with the medical safety regulations, or with product liability and other safety laws.

http://www.conformity.com/artman/publish/printer_feature247.shtml

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EP in 2nd Edition

“Although this Standard is primarily concerned with safety, it contains some requirements regarding reliable operation where this is connected with safety.”

Example:

42.3 APPLIED PARTS of equipment not intended to supply heat to a PATIENT shall not have surface temperatures exceeding 41°C.

2.9.12 During the test Thermal cut-outs shall not be de-activated and shall not operate

EP is compliance with operational test requirements of IEC60601-1 2nd Edition,

+

IEC60601 collateral and particular standards.

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EP for EMC in 2nd Edition

IEC60601-1-2:2001 (2nd Edition, mandatory since 2004) already has term ESSENTIAL PERFORMANCE taken from draft of IEC60601-1:2005.

It allows a risk analysis to be used to determine the EP and safety of MD that must be examined during IMMUNITY testing, and

whether testing according to this standard is required for non-medical electrical equipment that is combined with MEDICAL ELECTRICAL EQUIPMENT to form a SYSTEM.

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EP for products with alarm conditions

If MD needs to notify the OPERATOR that a HAZARDOUS SITUATION can exist, then MD "shall include an ALARM SYSTEM complying with this collateral standard for that purpose."

The definition of ALARM CONDITION is

"state of the ALARM SYSTEM when it has determined that a potential or actual HAZARD exists".

If you determined that such state exists, then EN / IEC 60601-1-8 is applicable.

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Alarm Signals

… and if applicable, you need to generate visual signal as specified below.

6.3 Generation of ALARM SIGNALS
6.3.1 General
Each ALARM CONDITION shall cause the generation of visual ALARM SIGNALS as specified in this collateral standard.

If deemed necessary by RISK ASSESSMENT regarding the environment in which the ALARM SYSTEM is intended to be used, additional ALARM SIGNALS shall be generated. These additional ALARM SIGNALS may be auditory, verbal, vibratory or produced by other means.

Please note the requirements of IEC 60601-1-8 standard relevant also to sound messages to patient (sound level, bandwidth and the like).

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Clinical Trials

MDD specifically states that for devices intended for the clinical investigations, manufacturer should provide "a statement that the device in question conforms to the essential requirements apart from the aspects covered by the investigations and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the patient."

Common interpretation is that the regulatory requirements should be checked in full (meaning compliance with EN60601-1 with all collateral standards).

In practice, we have numerous cases when partial testing was accepted.

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Finding right balance

Compliance with a standard offers a very good claim that the product was indeed safe, but …

as the British Standards Institute states in the preamble to all its type test standards,

“compliance with a British Standard does not of itself confer immunity from legal obligations”.

1. **Use a Good Practice: GMP/GLP/GCP and the like.**
2. **Make your own Project Risk Assessment and Risk Mitigation Plan**

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Conclusions, Part I

For some MDs, compliance to 3rd Edition is now the only option to obtain regulatory approval!

Various national regulators accept 3rd Edition, and have already announced withdraw date for 2nd Edition.

For various product categories, safety assessment becomes state-of-the-art project with major time and cost implications.

Always review your contract with test lab to understand SOW. It is not only Certificate of Compliance, but also Test Report and its content!

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Part II
Electromagnetic compatibility (EMC) requirements for Medical Devices

Presented by: Mr. Michael Nikishin,
Hermon Laboratories
EMC & Radio Group Manager

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Essential requirements

under 93/42/EEC Medical Devices Directive (MDD)

Annex I

I. GENERAL REQUIREMENTS

1. The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, users or other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.
2. The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.
3. The devices must achieve the performances intended by the manufacturer and be designed
4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected when the device is subjected to the stresses which can occur during normal conditions of use…

II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION

11. Protection against radiation

11.1. General: Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

11.2. Intended radiation

11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.

11.2.2. Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.

11.3. Unintended radiation: Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.

11.4. Instructions: The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

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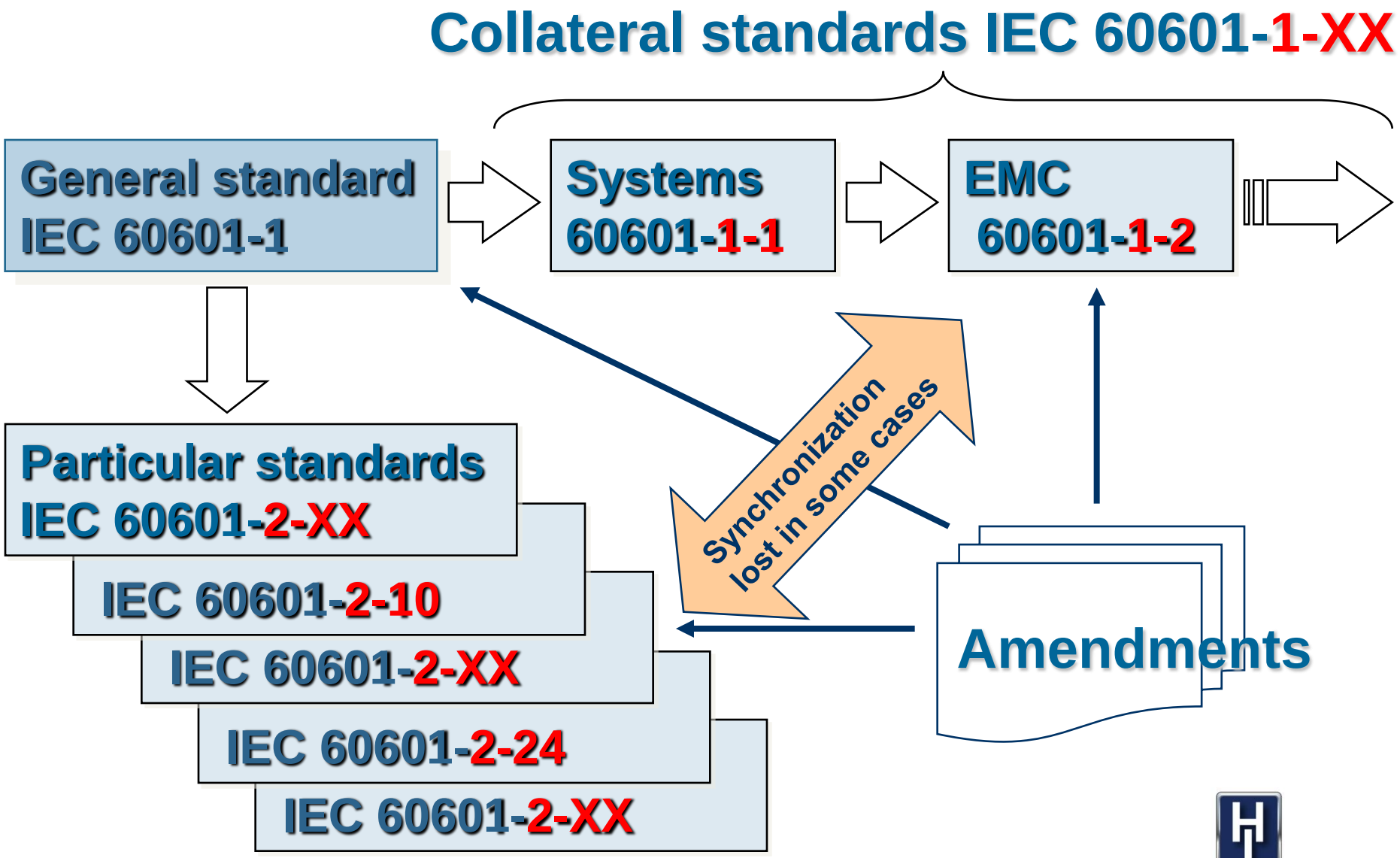
IEC 60601-X-XX Standards structure



Some particular standards provide additional set up requirements and/or test limits for EMC

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ELECTROMAGNETIC COMPATIBILITY (Section 4.1.1)

ME EQUIPMENT and ME SYSTEMS shall not emit ELECTROMAGNETIC DISTURBANCES that could affect radio services, other equipment or the ESSENTIAL PERFORMANCE of other ME EQUIPMENT and ME SYSTEMS.

ME EQUIPMENT and ME SYSTEMS shall have adequate IMMUNITY to be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of ELECTROMAGNETIC DISTURBANCES.

Consider compliance to exist if the requirements of this collateral standard are met.

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Emission limits

Reference standard		Port	Test level	
Test	Procedure			
Radiated emissions	CISPR 11	Enclosure	Group 1	Class A
				Class B
			Group 2	Class A
				Class B
Conducted emissions	CISPR 11	AC power	Group 1	Class A
				Class B
			Group 2	Class A
				Class B
Current Harmonics	IEC 61000-3-2	AC power	IEC 61000-3-2	
Voltage fluctuations and flickers	IEC 61000-3-3	AC power	IEC 61000-3-3	

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Immunity test levels

Reference standard		Port	Test level		
Test	Procedure				
ESD	IEC 61000-4-2	Enclosure		Contact Air	2, 4, 6 kV 2, 4, 8 kV
RI to RF fields	IEC 61000-4-3	Enclosure	0.15-80 MHz	AM 80% 1 kHz or AM 80% 2 Hz	3 or 10 V/m (Life support)
EFT	IEC 61000-4-4	AC power DC power* Other lines*	5 kHz	5/50 ns	2.0 kV 2.0 kV 1.0 kV
Surge	IEC 61000-4-5	AC power	Differential Common	0 Ω (2 Ω) 10 Ω (12 Ω)	0.5/1.0 0.5/1.0/2.0
CI to RF fields	IEC 61000-4-6	AC power DC power** Other lines**	0.15-80 MHz	AM 80% 1 kHz or AM 80% 2 Hz	3 or 10 V_{RMS} (Life support)
Magnetic fields	IEC 61000-4-8	Enclosure		50/60 Hz	3 A/m
Voltage dips and interruptions	IEC 61000-4-11	>95% 60% 30% >95%		10 ms 100 ms 500 ms 5000 ms	<11.5V_{RMS} 92 V_{RMS} 161 V_{RMS} <11.5 V_{RMS}

** - Applies only to ports which may be connected to cables longer than 3 meters*

*** - Applies only to ports which are connected to cables longer than 1 meters*

Test conditions (Interpretation sheet SC 62A/Publication IEC 60601-1-2(2007), 3rd edition/I-SH 01)

Test name	Test conditions
Emissions	
Radiated emissions	At any nominal power voltage/frequency (one is enough)*???
Conducted emissions	At any nominal power voltage/frequency (one is enough)*???
Harmonic distortion	At 230 V / 50 Hz only (100 VAC for Japan)*
Voltage fluctuations and flicker	At 230 V / 50 Hz only (100 VAC for Japan)*
Immunity	
Electrostatic discharge (ESD)	At any nominal power voltage/frequency (one is enough)*
Radiated RF EM fields (RI)	At any nominal power voltage/frequency (one is enough)*
Electrical fast transients and bursts (EFT/B)	At the minimum and maximum nominal voltages, any operating frequency*
Surges	At the minimum and maximum nominal voltages, at any operating frequency*
Conducted RF EM fields (CI)	At any nominal power voltage/frequency (one is enough)*
Voltage dips, short interruptions and variations	At the minimum and maximum nominal voltages, but at the minimum power frequency (50 Hz) only*
Magnetic fields	At all nominal power frequencies but at any power voltage (same frequency as applied field)*

Non-medical electrical equipment (Section 4.1.2)

- **Electrical equipment that is not ME EQUIPMENT and that is supplied as part of an ME SYSTEM is exempt from the EMC testing requirements of this collateral standard provided that the following conditions are met**
  - the electrical equipment that is not ME EQUIPMENT complies with applicable international EMC standards
  - both the EMISSIONS and IMMUNITY of the electrical equipment that is not ME EQUIPMENT have been determined not to adversely affect the BASIC SAFETY or ESSENTIAL PERFORMANCE
  - the EMISSIONS of the electrical equipment that is not ME EQUIPMENT have been determined not to cause the EMISSIONS of the ME SYSTEM to exceed applicable limits
  - Check compliance by inspection of the documents

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Separation into groups

- Group 1 equipment contains all equipment in the scope of this standard which is not classified as group 2 equipment. Most types of ME EQUIPMENT and ME SYSTEMS generate or use RF energy only for their internal functioning and therefore belong to group 1.

- Group 2 equipment: contains equipment in which RF energy is intentionally generated and applied, in the form of electromagnetic radiation, inductive and/or capacitive coupling, to patients. Only a few EQUIPMENT apply RF energy to PATIENTS and are therefore members of group 2.

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Group 1 equipment

- Group 1 equipment contains all equipment in the scope of this standard which is not classified as group 2 equipment. Most types of ME EQUIPMENT and ME SYSTEMS generate or use RF energy only for their internal functioning and therefore belong to group 1.
  - Electro- and magneto-cardiography EQUIPMENT
  - Electro- and magneto-encephalography EQUIPMENT
  - Electro- and magneto-myography EQUIPMENT
  - EQUIPMENT intended to deliver energy to the PATIENT, but in a form that is other than RF electromagnetic

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Group 2 equipment

- Group 2 equipment: group 2 contains equipment in which RF energy is intentionally generated and applied, in the form of electromagnetic radiation, inductive and/or capacitive coupling, to patients. Only a few EQUIPMENT apply RF energy to PATIENTS and are therefore members of group 2.
  - MRI
  - Therapy EQUIPMENT
  - Diathermy EQUIPMENT (short wave, ultra-short wave, microwave therapy EQUIPMENT)
  - Hyperthermy EQUIPMENT
  - High frequency surgical EQUIPMENT

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Class A and B installation environment

Standard	Installation environment			
	Home/ Domestic	Office/ Light industry	Hospitals	Industry
Generic standards EN 61000-6-X	Class B	Class B	NA	Class A
Medical standard EN 60601-1-2	Class B	Class A	Class A	Class A
The rest of standards EN55022, EN55011, EN300 386, EN61326, EN 301 489-X…	Class B	Class A	NA	Class A

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Emissions test mode selection

The main concern:

Maximum power under the **greatest activity**

- ✓ The highest **transmission power**
- ✓ The highest **data rate**
- ✓ The highest **power consumption**
- ✓ Maximum **cables configuration**
- ✓ Maximum **load conditions**

Equipment provided for the test shall be a r**epresentative of production model** including the final layouts and final SW revisions

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Immunity test mode selection

The main concern:

Maximum gain (sensitivity) under the **greatest activity**

- ✓ The highest **receiving gain**
- ✓ The highest **data rate**
- ✓ All modules **exersised frequently**
- ✓ Maximum **cables configuration**
- ✓ The minimum sufficient **receive power** **(**minimum signal to noise specification)

Equipment provided for the test shall be a r**epresentative of production model** including the final layouts, SW may be modified to allow **frequent monitoring** of the EUT performance

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ESSENTIAL PERFORMANCE IEC 60601-1:2005 Section 4.3

- The MANUFACTURER shall identify which functions of the ME EQUIPMENT and ME SYSTEMS are ESSENTIAL PERFORMANCE
- Where this standard specifies that ESSENTIAL PERFORMANCE is to be maintained following a particular test, these functions shall be used and compliance shall be checked by inspection, and if necessary, by functional test
- Where requirements of this standard refer to ESSENTIAL PERFORMANCE, that ESSENTIAL PERFORMANCE is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for RISK acceptability
- *Compliance is checked by inspection of the RISK MANAGEMENT FILE*

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Section 5: Identification, marking and documents

- **Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (section 5.1)**
  - **5.1.1 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts that include RF transmitters or that apply RF electromagnetic energy for diagnosis or treatment**

  - **5.1.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts for which the connector testing exemption specified in 6.2.2.2 c) is used**

  - **5.1.3 Marking on the outside of ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location**

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Section 5: Identification, marking and documents

ACCOMPANYING DOCUMENTS (section 5.2)

- 5.2.2.1 Requirements applicable to all EQUIPMENT
- 5.2.2.2 Requirements applicable to EQUIPMENT other than those specified for use only in a shielded location
- 5.2.2.3 Requirements applicable to EQUIPMENT specified for use only in a shielded location
- 5.2.2.4 Requirements applicable to that intentionally apply RF energy for diagnosis or treatment
- 5.2.2.5 Requirements applicable to EQUIPMENT that intentionally receive RF electromagnetic energy for the purpose of their operation
- 5.2.2.6 Requirements applicable to EQUIPMENT that include RF transmitters
- 5.2.2.7 Requirements applicable to cables, transducers and other ACCESSORIES
- 5.2.2.8 Requirements applicable to LARGE, PERMANENTLY-INSTALLED EQUIPMENT
- 5.2.2.9 Requirements applicable to EQUIPMENT found to have no ESSENTIAL PERFORMANCE
- 5.2.2.10 Requirements applicable to TYPE A PROFESSIONAL EQUIPMENT

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Technical description (Section 5.2.2)

- A list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES
- A warning that the use of ACCESSORIES, transducers and cables other than those specified may adversely effect EMC
- Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS
- A warning that the ME EQUIPMENT or ME SYSTEM should not be used adjacent to or stacked with other equipment
- A justification for each COMPLIANCE LEVEL that is lower than the IEC 60601 TEST LEVEL
- Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY
- The performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE

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Accompanying documents

- Instructions for use
- Technical description
- Guidance and manufacturer declaration- Electromagnetic emissions

  (life supporting and not life supporting equipment)
- Guidance and manufacturer declaration- Electromagnetic immunity

  (life supporting and not life supporting equipment)
- Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

  (life supporting and not life supporting equipment)

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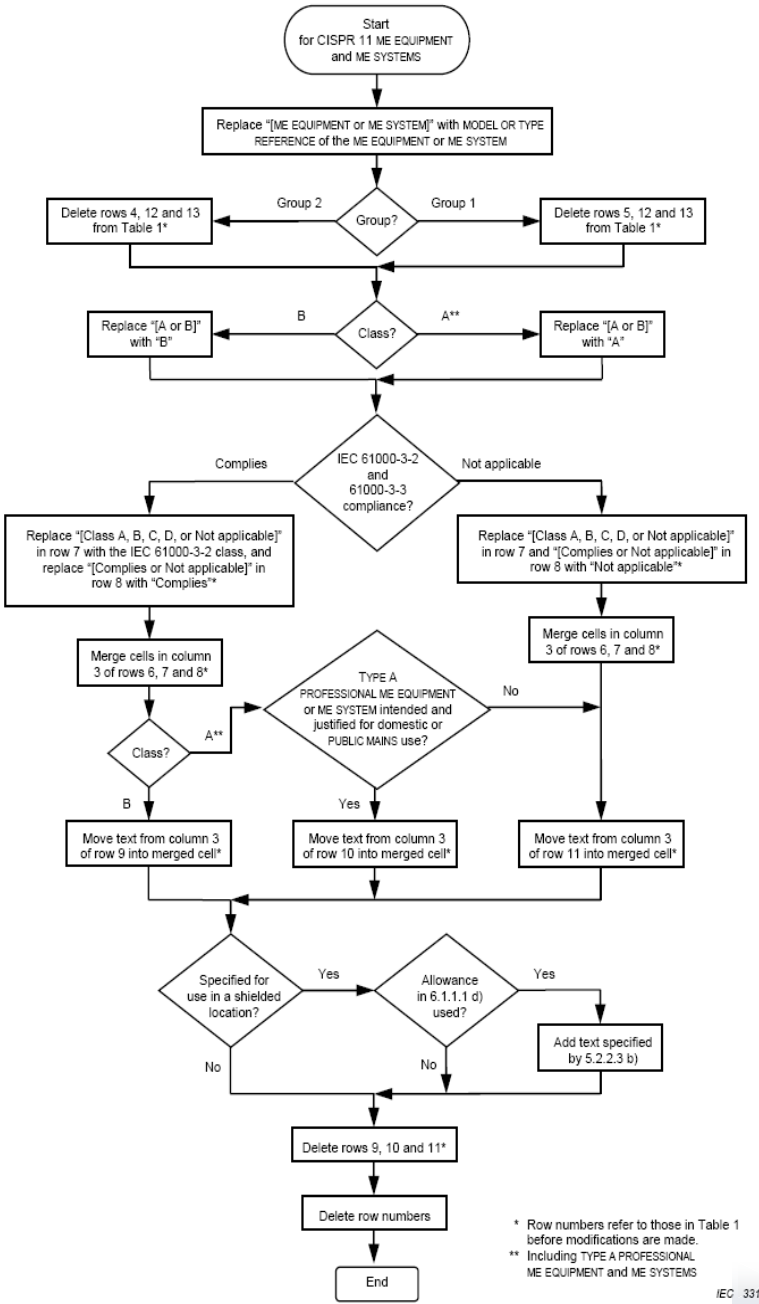
Guidance and manufacturer's declaration – electromagnetic EMISSIONS

Row			
1	**Guidance and manufacturer's declaration – electromagnetic emissions**		
2	The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment – guidance**
4	RF emissions CISPR 11	Group 1	The [ME EQUIPMENT or ME SYSTEM] uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Group 2	The [ME EQUIPMENT or ME SYSTEM] must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
6	RF emissions CISPR 11	Class [A or B]	
7	Harmonic emissions IEC 61000-3-2	[Class A, B, C, D, or Not applicable]	
8	Voltage fluctuations/ flicker emissions IEC 61000-3-3	[Complies or Not applicable]	
9		[See 5.2.2.1 c) and Figure 1]	The [ME EQUIPMENT or ME SYSTEM] is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
10		[See 5.2.2.1 c) and Figure 1]	The [ME EQUIPMENT or ME SYSTEM] is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM] or shielding the location.
11		[See 5.2.2.1 c) and Figure 1]	The [ME EQUIPMENT or ME SYSTEM] is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
12	RF emissions CISPR 14-1	Complies	The [ME EQUIPMENT] is not suitable for interconnection with other equipment.
13	RF emissions CISPR 15	Complies	The [ME EQUIPMENT] is not suitable for interconnection with other equipment.


Start for CISPR 11 ME EQUIPMENT and ME SYSTEMS
Replace "[ME EQUIPMENT or ME SYSTEM]" with MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM
Group?
Group 2
Group 1
Delete rows 4, 12 and 13 from Table 1*
Delete rows 5, 12 and 13 from Table 1*
Class?
B
A**
Replace "[A or B]" with "B"
Replace "[A or B]" with "A"
IEC 61000-3-2 and 61000-3-3 compliance?
Complies
Not applicable
Replace "[Class A, B, C, D, or Not applicable]" in row 7 with the IEC 61000-3-2 class, and replace "[Complies or Not applicable]" in row 8 with "Complies"*
Replace "[Class A, B, C, D, or Not applicable]" in row 7 and "[Complies or Not applicable]" in row 8 with "Not applicable"*
Merge cells in column 3 of rows 6, 7 and 8*
Merge cells in column 3 of rows 6, 7 and 8*
Class?
A**
B
TYPE A PROFESSIONAL ME EQUIPMENT or ME SYSTEM intended and justified for domestic or PUBLIC MAINS use?
No
Yes
Move text from column 3 of row 9 into merged cell*
Move text from column 3 of row 10 into merged cell*
Move text from column 3 of row 11 into merged cell*
Specified for use in a shielded location?
Yes
Allowance in 6.1.1.1 d) used?
Yes
No
No
Add text specified by 5.2.2.3 b)
Delete rows 9, 10 and 11*
Delete row numbers
End
* Row numbers refer to those in Table 1 before modifications are made.
** Including TYPE A PROFESSIONAL ME EQUIPMENT and ME SYSTEMS
IEC 331/07

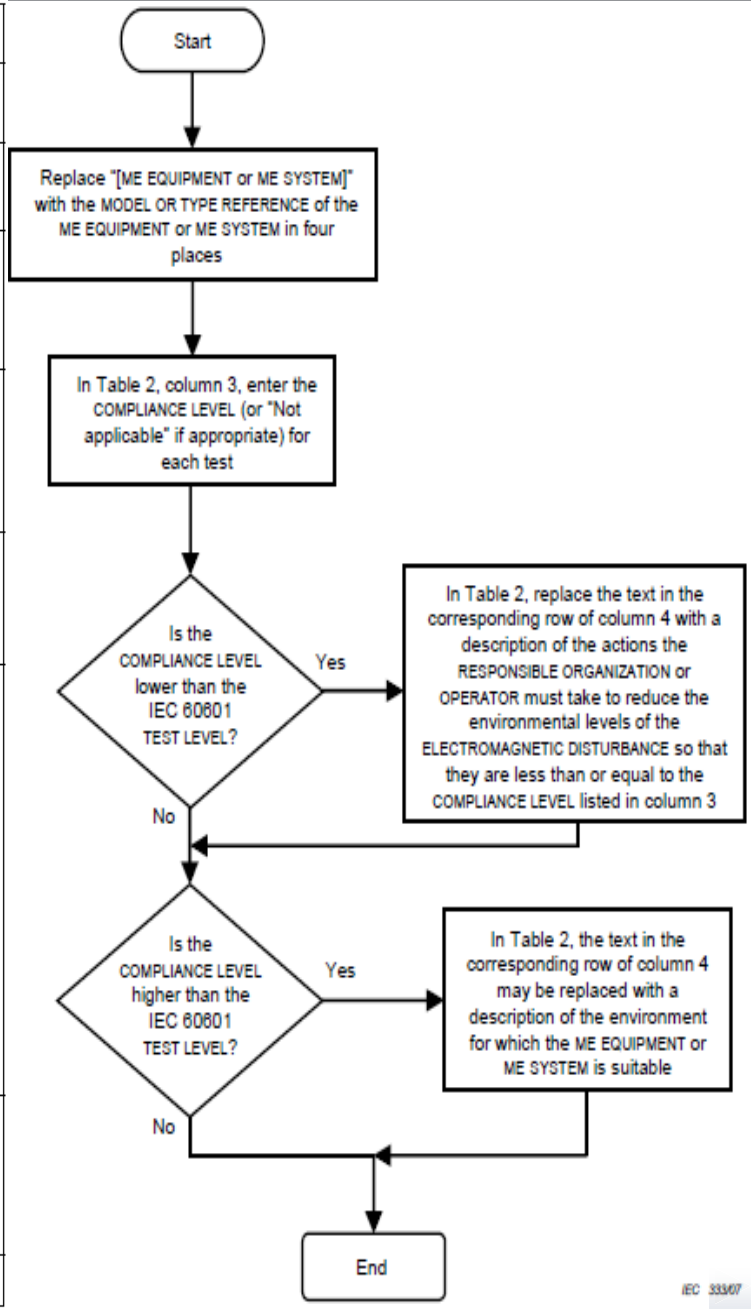
Guidance and manufacturer's declaration – electromagnetic IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity

The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s		Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.


Start
Replace "[ME EQUIPMENT or ME SYSTEM]" with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM in four places
In Table 2, column 3, enter the COMPLIANCE LEVEL (or "Not applicable" if appropriate) for each test
Is the COMPLIANCE LEVEL lower than the IEC 60601 TEST LEVEL?
Yes
In Table 2, replace the text in the corresponding row of column 4 with a description of the actions the RESPONSIBLE ORGANIZATION or OPERATOR must take to reduce the environmental levels of the ELECTROMAGNETIC DISTURBANCE so that they are less than or equal to the COMPLIANCE LEVEL listed in column 3
No
Is the COMPLIANCE LEVEL higher than the IEC 60601 TEST LEVEL?
Yes
In Table 2, the text in the corresponding row of column 4 may be replaced with a description of the environment for which the ME EQUIPMENT or ME SYSTEM is suitable
No
End
IEC 333/07

Guidance and manufacturer's declaration – RF fields IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity

The [ME EQUIPMENT or ME SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] should assure that it is used in such an environment.

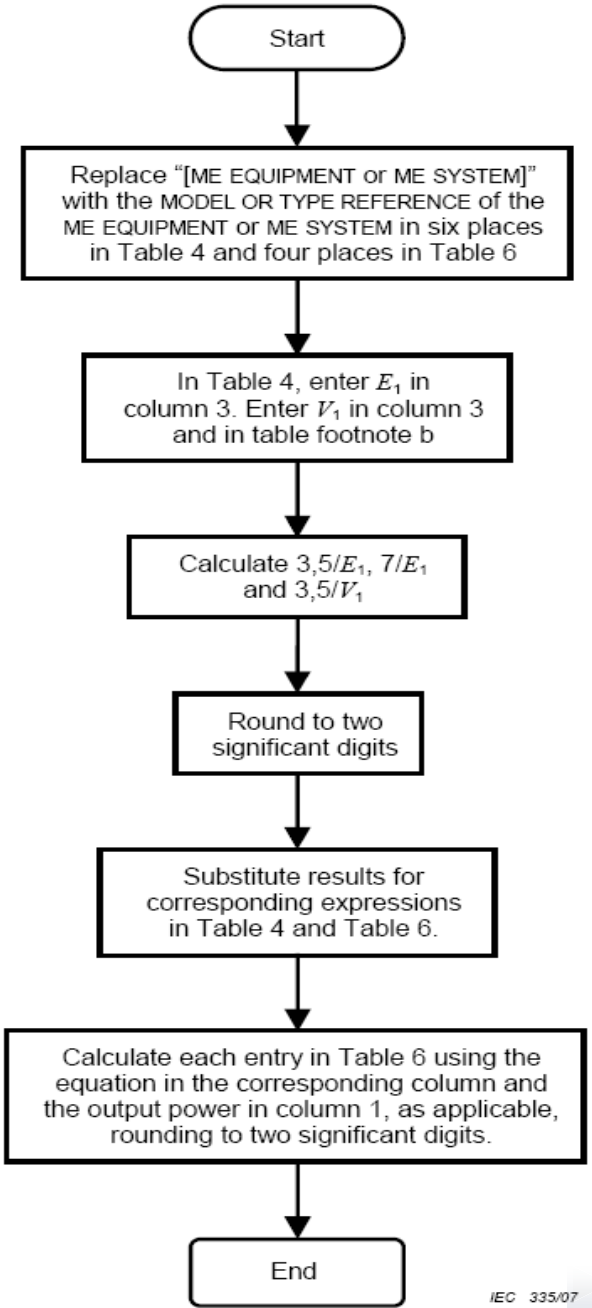
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT or ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	$[V_1]$ V	$d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	$[E_1]$ V/m	$d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM].

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.


Start
Replace "[ME EQUIPMENT or ME SYSTEM]" with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM in six places in Table 4 and four places in Table 6
In Table 4, enter E_1 in column 3. Enter V_1 in column 3 and in table footnote b
Calculate $3,5/E_1$, $7/E_1$ and $3,5/V_1$
Round to two significant digits
Substitute results for corresponding expressions in Table 4 and Table 6.
Calculate each entry in Table 6 using the equation in the corresponding column and the output power in column 1, as applicable, rounding to two significant digits.
End
IEC 335/07

Recommended separation distances guide

Recommended separation distances between portable and mobile RF communications equipment and the [ME EQUIPMENT or ME SYSTEM]

The [ME EQUIPMENT or ME SYSTEM] is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [ME EQUIPMENT or ME SYSTEM] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [ME EQUIPMENT or ME SYSTEM] as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E_1}]\sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{23}{E_1}]\sqrt{P}$
0,01				
0,1				
1				
10				
100				

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Part III (13:30-14:45)

Zoom-in on critical changes.

- Home Healthcare
- Changes in Technical Requirements
- Component selection for target market.
- How to work with ISO 14971.

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Changes in scope of 3rd Edition

The scope of IEC 60601-1 was significantly modified and expanded by deleting the phrase "under medical supervision" from the definition of medical electrical equipment, and adding "or compensation or alleviation of disease, injury or disability".

A collateral standard IEC 60601-1-XX becomes a normative part of the general standard on the date of its publication.

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Home Healthcare

IEC 60601-1-11:2010 is the newest Collateral Standard to the 3rd Edition. Published in April as IEC and already a MUST for MDD.

Title: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Good presentation by Dave Osborn, Philips Healthcare Sector Standards and Regulations Secretary, JWG6-Home Healthcare

http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM214274.pdf

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Home Healthcare Environment

Any environment that is NOT a professional healthcare facility (where OPERATORS with medical training are continually available).

NO PROTECTIVE EARTH connection only floating type applied parts permitted, unless the equipment is permanently installed by an electrician.

Equipment intended for the home healthcare environment must be Class B with respect to emissions.

The usability evaluation is required.

ENCLOSURES must be at least IP21 (light rain proof).

TRANSIT-OPERABLE, HANDHELD, and BODY-WORN equipment must be at least IP22.

Do not seal battery compartments!

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International Approvals for Home Healthcare

Before IEC 60601-1-11 manufacturers of healthcare equipment intended for use in homes have been required to comply with

Europe:	**EN60335-1 with particular standards**
N. America:	**UL60601-1 or UL1431**
ROW:	**IEC60335-1 or IEC 60601-1**

After IEC 60601-1-11 which covers most home healthcare equipment, some devices may still be subject to the requirements of other standards.

For example, UL1431 "Personal Hygiene and Health Care Appliances" covers household electric products for hygiene or other healthcare applications rated at 250 V or less. Products covered under this standard include hydromassage units, nebulizers, breast pumps, toothbrushes and contact lens disinfectors.

Europe:	**EN60601-1 3rd Ed. With EN60601-1-11**
N. America:	**ANSI60601-1 with IEC60601-1-11, or UL1431**
ROW:	**IEC60335-1 or IEC 60601-1 2nd Ed**

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International Approvals: CB scheme

CB Scheme proved itself as most reputable.

Also, governmental bodies act as NCBs in CB Scheme and as such have to accept CB test reports.

Example:

Importers to Israel of MAINS powered Home Healthcare equipment need to test sample at SII or provide CB or TUV (!) Certificate and Report to IEC60601-1 to get Import Permit.

To qualify product for exemption from SII Import Permit for limited import (mostly for private use), importer needs to file request with Ministry of Industry, Trade and Labor and attach CB Certificate and Report.

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Changes in technical requirements

Significant changes in technical requirements in body of the standard.

- **More liberal view on isolation requirements for the Operator**
- **(IEC 60950-1)**
- **Incorporates collateral standards for System (60601-1-1) and SW (60601-1-4)**
- **Incorporates particular standard for total patient leakage current (60601-2-49)**
- **Compliance requirements for Non-hazardous Lasers**
- **More liberal view on temperatures on Applied Parts**
- **Other changes**

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Non-medical electrical equipment

One of the most advertised technical changes in 3rd Edition is the relaxation of operator protection requirements, which makes for significant savings on the cost of medical equipment.

For example, if a device or its components do not touch the patient, then that device or its components only need to meet the less stringent insulation and leakage requirements of IEC 60950-1 (ITE).

What about EMC? Most probably, ITE device or its components do not comply with immunity requirements of MD.

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Normative references

Always has been and still remains a problem!

2nd Ed: Particular standards may be synchronized with withdrawn collateral standard, like IEC60601-2-24:1996 (still in force) is based on IEC60601-1-2:1993.

3rd Ed: "The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies."

IEC 60950-1:2001, Information technology equipment – Safety – Part 1: General requirements

IEC 60825-1:1993, Safety of laser products – Part 1: Equipment classification, requirements and user's guide, with Amendment 1 (1997) and Amendment 2 (2001)

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Zoom in on IEC 60950-1:2001

2005: IEC60950-1 2nd Edition is published and can be used as alternative for superseded IEC60950-1 1st Edition for CB Scheme

2006: IEC60950-1 2nd Edition is adopted as EN60950-1:2006

2007: IEC60950-1 2nd Edition is adopted as UL/CSA60950-1:2007, and EN60950-1:2006 is Listed in OJ in 2007 (R&TTE)

2008: EN60950-1:2006 is Listed in OJ in 2008 (LVD)

2010: On December 1st EN/UL/CSA 60950-1:2001 and its amendment are withdrawn.

IEC60950-1 1st Edition may still be used as a national standard by other countries also after 2010. But most component manufacturers will move after N. America and European Markets, and certify components to EN/UL/CSA 60950-1 2nd Edition.

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11.3 Fire enclosures

IEC 60601-1 2nd Edition has no requirements.

UL 60601-1 has flammability requirements for parts of enclosure (V-2 for transportable equipment and V-0 for fixed equipment).

In the 3rd Edition, the requirements are:

- **Internal parts: FV-1 for wire; FV-2 for connectors, printed circuit boards, insulation.**
- **Enclosure: FV-2 for transportable & FV-1 for fixed equipment.**
- **Bottom of fire enclosure rules are aligned with IEC 60950-1.**

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4.8 Components

All components, including wiring, the failure of which could result in a hazard, shall be used in accordance with their specified ratings unless a specific exception is made in the standard or through the RISK MANAGEMENT PROCESS.

As the end-use equipment manufacturer, you become responsible for ALL safety aspects of complete equipment and its installation, even those of incorporated certified components.

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Component approval

The reliability of components that are used as means of protection shall be assessed for the conditions of use in the product. They shall comply with one of the following :

- **the applicable safety requirements of a relevant IEC or ISO standard;**
- **where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.**

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Component selection for CB approval.

CB rules for components acceptance define 4 potential situations for component requirements:

- **There is an existing IEC standard for the component;**
- **There is no IEC standard but there is a regional or national standard for the component;**
- **No component requirements exists;**
- **The end-product standard contains component requirements.**

http://www.iecee.org/Operational_documents/iecee_documents/od-cb2039_ed.1.0.pdf

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Component selection

Introduction of concept “component approval” can create a gap between your expectations for coverage of component assessment, and actual testing performed.

The same consideration is inherent to UL’s Recognized Component Conditions of Acceptability (CoA).

Components covered under UL Component Recognition Mark program are considered incomplete and are intended to be installed into another device, system or end-product.

New-tech published our article on component selection in MAINS
http://new-techonline.com/nt-mag/2010/05/%d7%91%d7%98%d7%99%d7%97%d7%95%d7%aa-%d7%97%d7%a9%d7%9e%d7%9c%d7%99%d7%aa-%d7%91%d7%9e%d7%95%d7%a6%d7%a8/

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Component approval considerations

“Plug and play” approach to using components in your end-use product will most likely not work.

Make sure to understand limitations of your components and prepare to cover them in end-use product investigation.

Certification level, Conditions of acceptability, Installation instructions and user manual of components and sub-assemblies must be obtained and reviewed.

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Component selection for CB and NRTL approval.

UL is not “worst case” for fuses, cables and power supplies any longer!

Using components approved to National Standards only (like UL 60601-1 for power supplies) can prevent obtaining CB Report.

CB and NRTL approval status for components and sub-assemblies should be provided ahead of investigation.

If component approvals are adequate and acceptable, CB, NRTL and CE projects should take the same timeframe.

Acceptance of construction or component is very much dependant on certification path.

Watch latest developments in IEC component standards.

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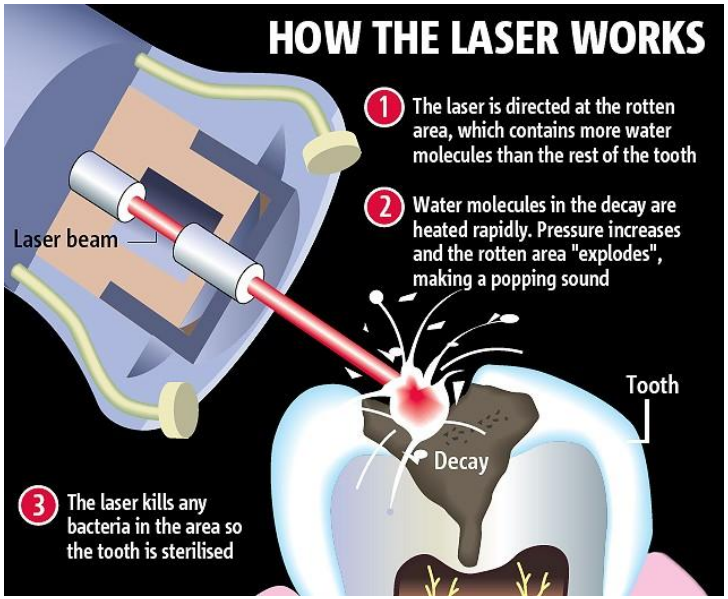
Zoom-in on Laser Products

There were no general requirements for most Radiation Hazards in 2nd Edition

Normal procedure is to add IEC 60825-1 as amendment, but not to mention it anywhere in CE DoC or on NRTL Certificate

3rd Edition requires compliance with IEC 60825-1:1993 (superseded in 2005).

New IEC60601-1-22 applies to laser equipment for either surgical, therapeutic, medical diagnostic, cosmetic, or veterinary applications, intended for its use on humans or animals, classified as a class 3B or class 4 laser product as defined by 3.22 and 3.23 in IEC 60825-1.


HOW THE LASER WORKS
1 The laser is directed at the rotten area, which contains more water molecules than the rest of the tooth
2 Water molecules in the decay are heated rapidly. Pressure increases and the rotten area "explodes", making a popping sound
Laser beam
Tooth
Decay
3 The laser kills any bacteria in the area so the tooth is sterilised

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Zoom-in on ESSENTIAL PERFORMANCE

Performance requirements for specific MD defined by manufacturer based on RISK ASSESSMENT.

+

In IEC60601-1 3rd Edition, it is compliance with constructional and test requirements of main standard

+

IEC60601 collateral and particular standards

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Risk Assessment

RISK ANALYSIS is systematic use of available information to identify HAZARDS and to estimate the RISK

RISK EVALUATION is a judgment, on the basis of RISK ANALYSIS, of whether a RISK which is acceptable has been achieved in a given context based on the current values of society

RISK ANALYSIS + RISK EVALUATION = RISK ASSESSMENT
overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

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Risk Control and Management

RISK CONTROL

PROCESS through which decisions are reached and protective measures are implemented for reducing RISKS to, or maintaining RISKS within, specified levels

Type or group of hazard	Origin	Unit / Module	Potential consequences	Comments	Initial assessment			sk Reducti
					Probability	Severity	Risk level	
Radiation hazards	Ionising radiation source		Burn	N/A	E-Not relevant	E-Not relevant	**No Risk**	
			Damage to eyes and skin	N/A	E-Not relevant	E-Not relevant	**No Risk**	
			Effects on reproductive capability	N/A	E-Not relevant	E-Not relevant	**No Risk**	
			Genetic mutation	N/A	E-Not relevant	E-Not relevant	**No Risk**	
			Headache, insomnia, etc	N/A	E-Not relevant	E-Not relevant	**No Risk**	
	Optical radiation (infrared, visible and ultraviolet), including laser	UV Lamp	Burn	N/A	E-Not relevant	E-Not relevant	**No Risk**	
			Damage to eyes and skin	Long term exposure	A-Very Likely	C-Moderate	**High**	
			Effects on reproductive capability	N/A	E-Not relevant	E-Not relevant	**No Risk**	
			Genetic mutation	N/A	E-Not relevant	E-Not relevant	**No Risk**	
			Headache, insomnia, etc	N/A	E-Not relevant	E-Not relevant	**No Risk**	

RISK MANAGEMENT

systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK

HERMON LABORATORIES

4.2 Risk Management Process

Requirement for the manufacturer of medical equipment and systems to have a formal risk management system that conforms to ISO 14971

There are more than 100 times where 3rd Edition requires to determine risk acceptability in applying a particular requirement.

Test Laboratory shall verify compliance on a product basis and fill in the checklist in the Technical Report Form (TRF).

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Risk Management File

The manufacturer shall compile documentation on known and foreseeable hazards associated with the MD in both normal and fault conditions.

Reasonably foreseeable sequences or combinations of events that can result in a hazardous situation shall be considered and the resulting hazardous situation(s) shall be recorded.

For each identified hazardous situation, the associated risk(s) shall be estimated using available information or data.

For each identified hazardous situation, the manufacturer shall decide, using the criteria defined in the risk management plan, if risk reduction is required.

The results of these activities shall be recorded in the risk management file.

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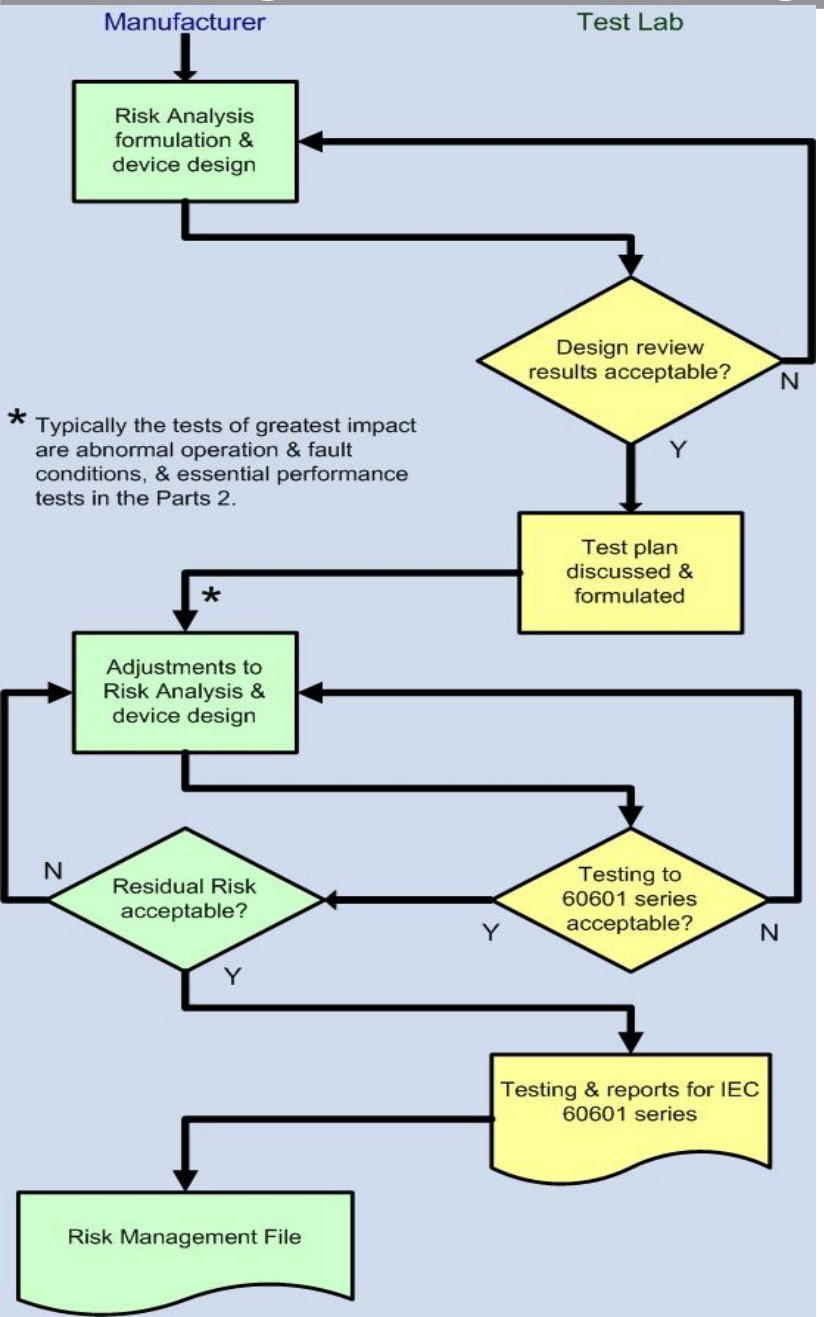
Working with Risk Management File



There are more than 100 times where 3rd Edition requires to determine risk acceptability in applying a particular requirement.

Test Laboratory shall verify compliance on a product basis and fill in the checklist in the Technical Report Form (TRF).

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ISO 14971 assessment

Requirement for the manufacturer of medical equipment and systems to have a formal risk management system that conforms to ISO 14971

There are two options how the requirements of ISO 14971 should be evaluated

- **review of a manufacturer‘s documentation, or**
- **on-site assessment of a manufacturer's risk management process**

A certificate for ISO14971 is certainly a useful asset, but it does not exempt the safety test lab from having to verify compliance on a product basis and filling TRF.

TRF contains some of the risk management requirements, but does not provide sufficient detail on the content .

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Technical report IEC/TR 62354

To synchronize testing procedures for medical electrical equipment based on 3rd Edition of IEC 60601-1 between various regulators and test labs, second edition of IEC/TR 62354 has been published in 2009.

This technical report (a guidance, not a standard) primarily covers the third edition of IEC 60601-1, but not collateral and particular standards.

ANSI/AAMI/IEC TIR62354:2009 - General testing procedures for medical electrical equipment, has been published a year ago (March 2010).

To establish uniformity between test laboratories in assessment of ISO 14971 requirements, the Risk Management Task Force (RMTF) has been established.

The main task is to detail the needed elements for "inspection of the risk management file" as called out in IEC 60601-1.

Based on this work, it is anticipated that the TRF will be modified.

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Conclusions, Part III

System approach has always been required, but 3rd Edition put more stress on it in form of risk management.

You need to understand your product environment to make proper component selection and provide expected level of safety.

Major aspects of essential performance and risk management are not synchronized between various regulators and test labs.

TRF is published and has been in use for several years now, but does not provide sufficient detail on the content of essential performance and risk analysis.

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Review of MD requirements for International market access

JAPAN

Information on the following slides is quoted from presentation "The Regulatory System for Importing Electrical /electronic Goods to Japan" by Mr. Kurt K. Heinz of NCB TÜV Rheinland Japan, presented on CB-Scheme Workshop in Tel-Aviv on 29 June 2010

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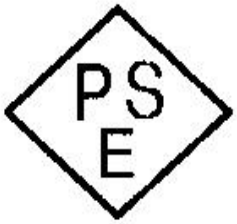
Contents

1. Electrical Appliance and Material Safety Law (DENAN Law)



2. New Pharmaceutical Affairs Law (PAL)

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Explanation for "Denki Yōhin" - Electrical Appliance and Materials

In the DENAN, "Denki Yōhin" is classified into two categories "Category A" and "Category B"

Category A product : Need to obtain "Certificate of Conformity (CoC) by Registered Conformity Assessment Body (RCAB) = Registered by Japanese Government.

Category B product : Not necessary to get CoC, but there is the obligation to conform to the Technical Requirements stipulated by the Ministerial Ordinance. Self-verification (confirmation) can be done by manufacturer.

NOTE: There are many other products not being in scope of DENAN Law. And, even if subjecting to DENAN, there are also products being in scope of another regulation, e.g., **therapeutic apparatus for households use**, microwave oven, etc.

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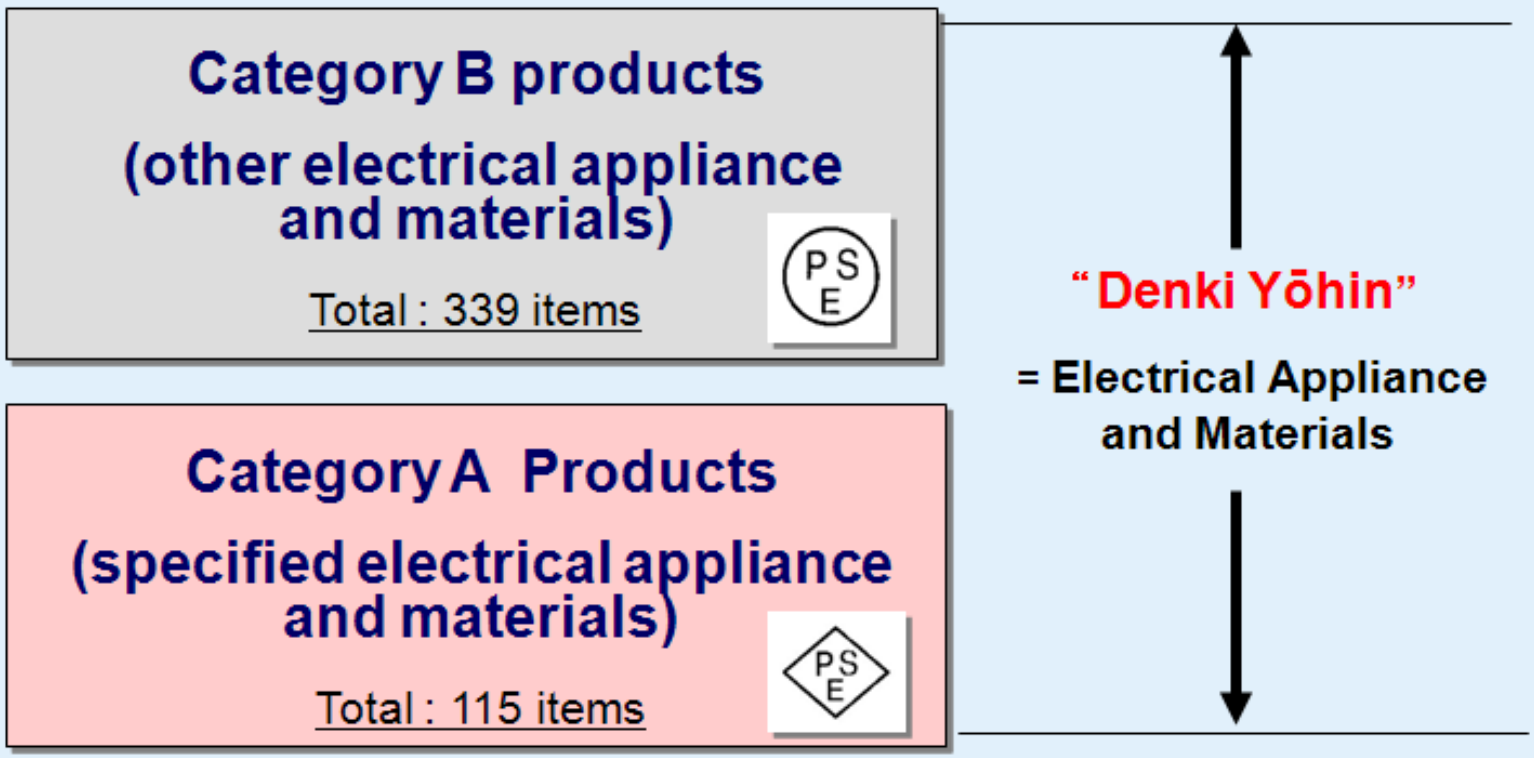
Product categories



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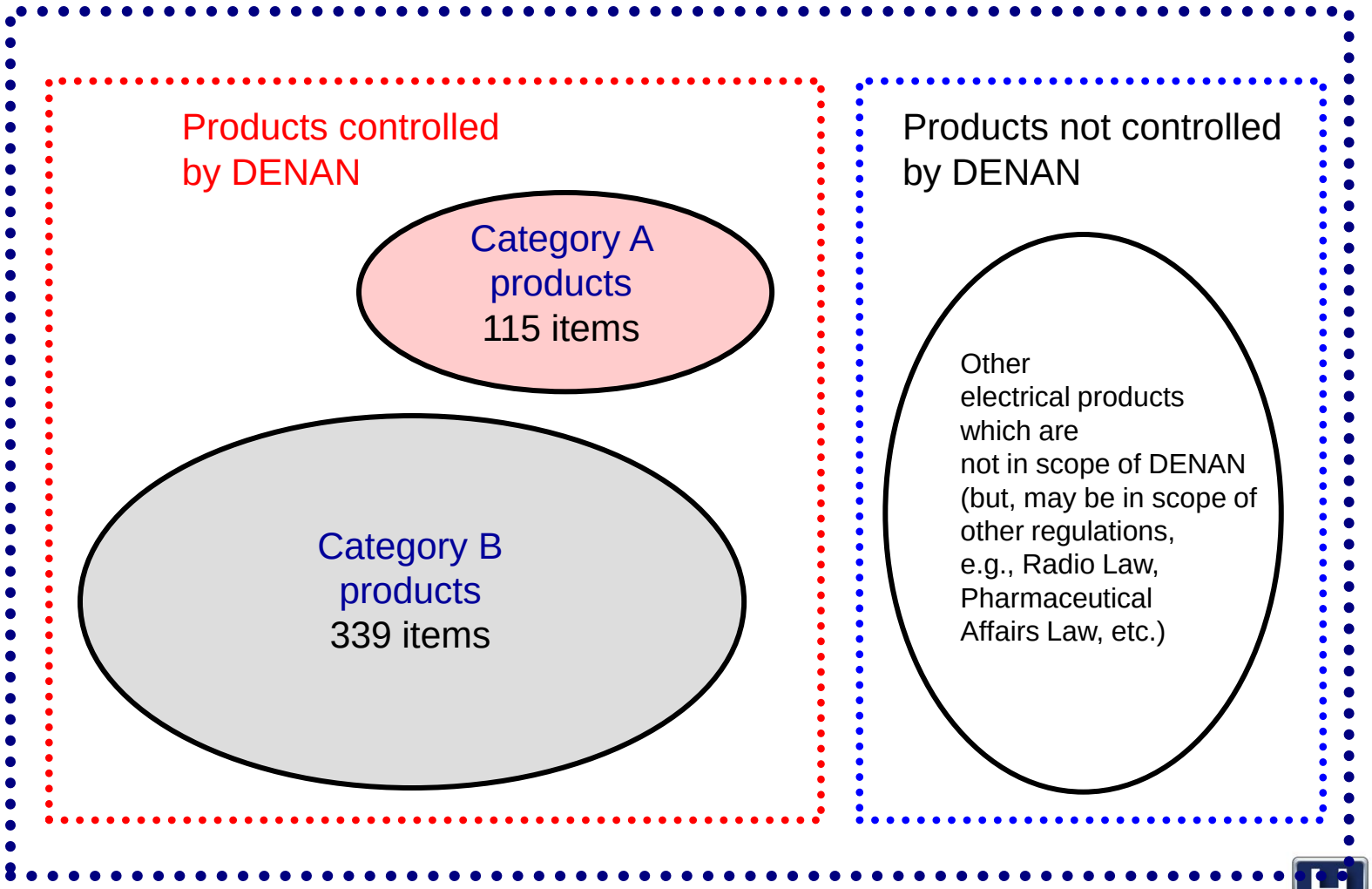
Electrical products in Japanese market


Products controlled by DENAN
Category A products
115 items
Category B products
339 items
Products not controlled by DENAN
Other electrical products which are not in scope of DENAN (but, may be in scope of other regulations, e.g., Radio Law, Pharmaceutical Affairs Law, etc.)

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Power Supply Device with DC Output

PS
E

Category A

AC Electrical Appliance
DC Power Supply Unit

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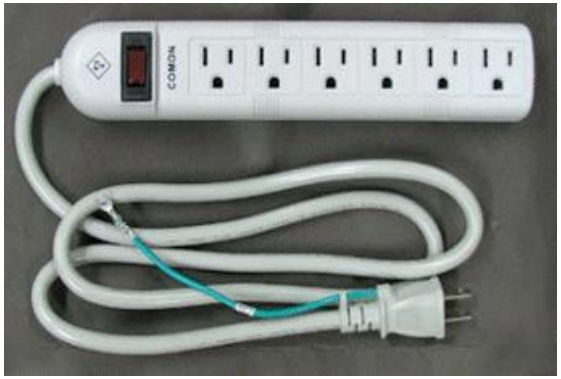
Extension Cord Set



Category A

Wiring Devices

Multi Tap, Cord, Attachment Plug (respective part)

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Hair Dryer

PSE

Category B

Electrical Motor Operated Appliance
Electric Hair Dryer

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Massage Chair

PS
E

Category A

Electrical Motor Operated Appliance

Electric Massager

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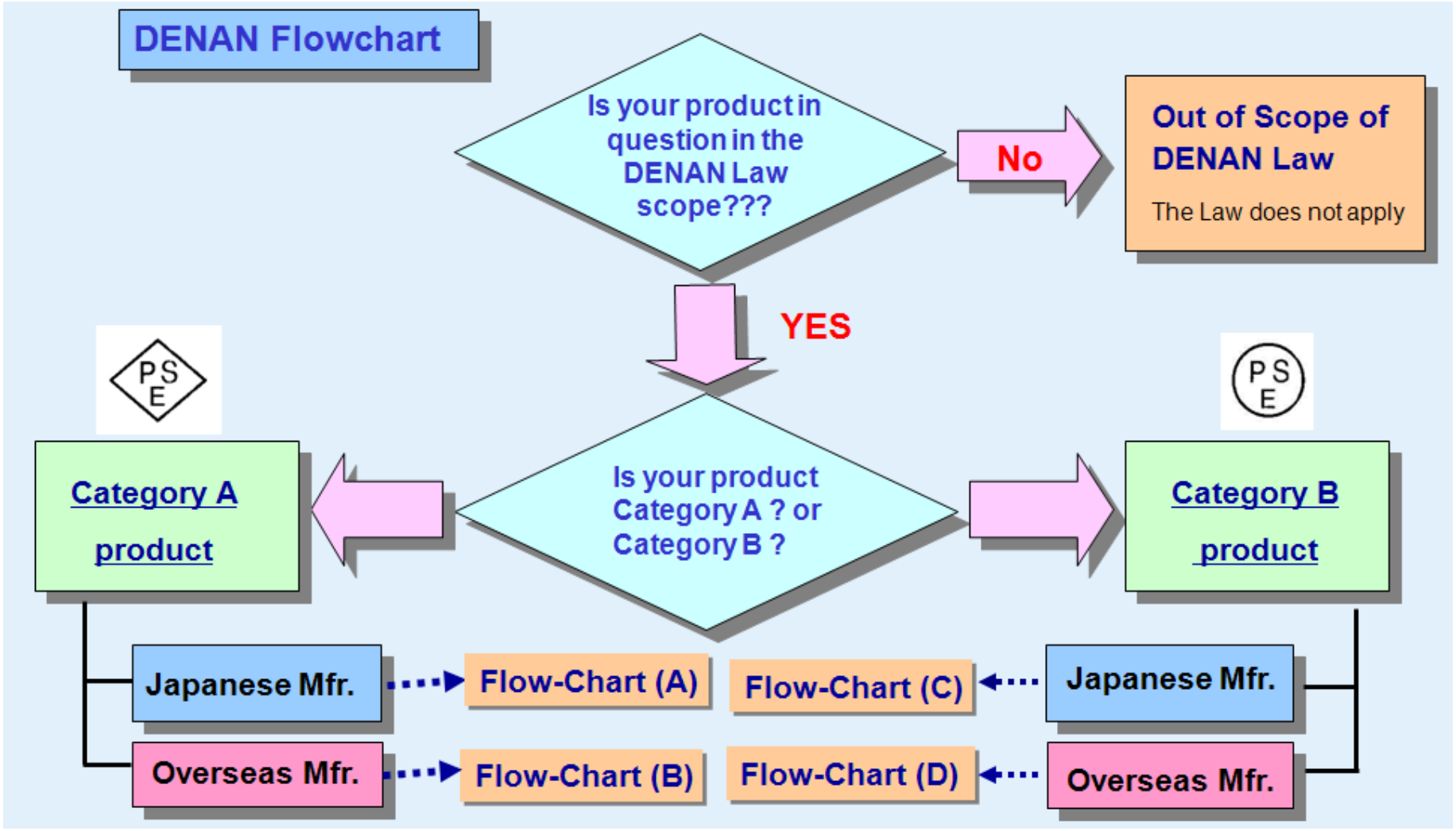

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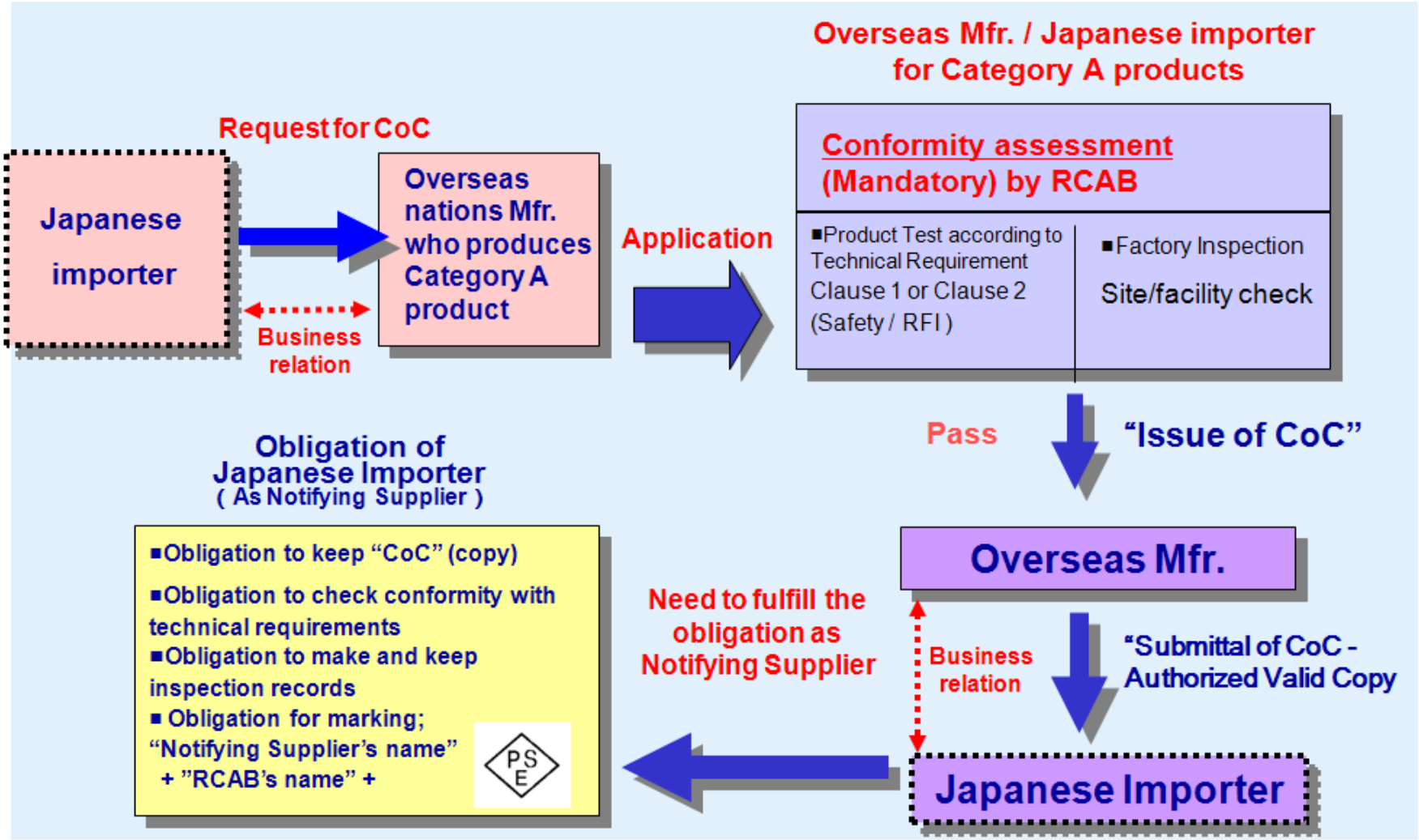
DENAN Flowchart (B)


Overseas Mfr. / Japanese importer for Category A products
Request for CoC
Japanese importer
Business relation
Overseas nations Mfr. who produces Category A product
Application
Conformity assessment (Mandatory) by RCAB
■Product Test according to Technical Requirement Clause 1 or Clause 2 (Safety / RFI)
■Factory Inspection Site/facility check
Pass
"Issue of CoC"
Obligation of Japanese Importer (As Notifying Supplier)
■Obligation to keep "CoC" (copy)
■Obligation to check conformity with technical requirements
■Obligation to make and keep inspection records
■ Obligation for marking; "Notifying Supplier's name" + "RCAB's name" +
PS E
Need to fulfill the obligation as Notifying Supplier
Overseas Mfr.
Business relation
"Submittal of CoC - Authorized Valid Copy
Japanese Importer

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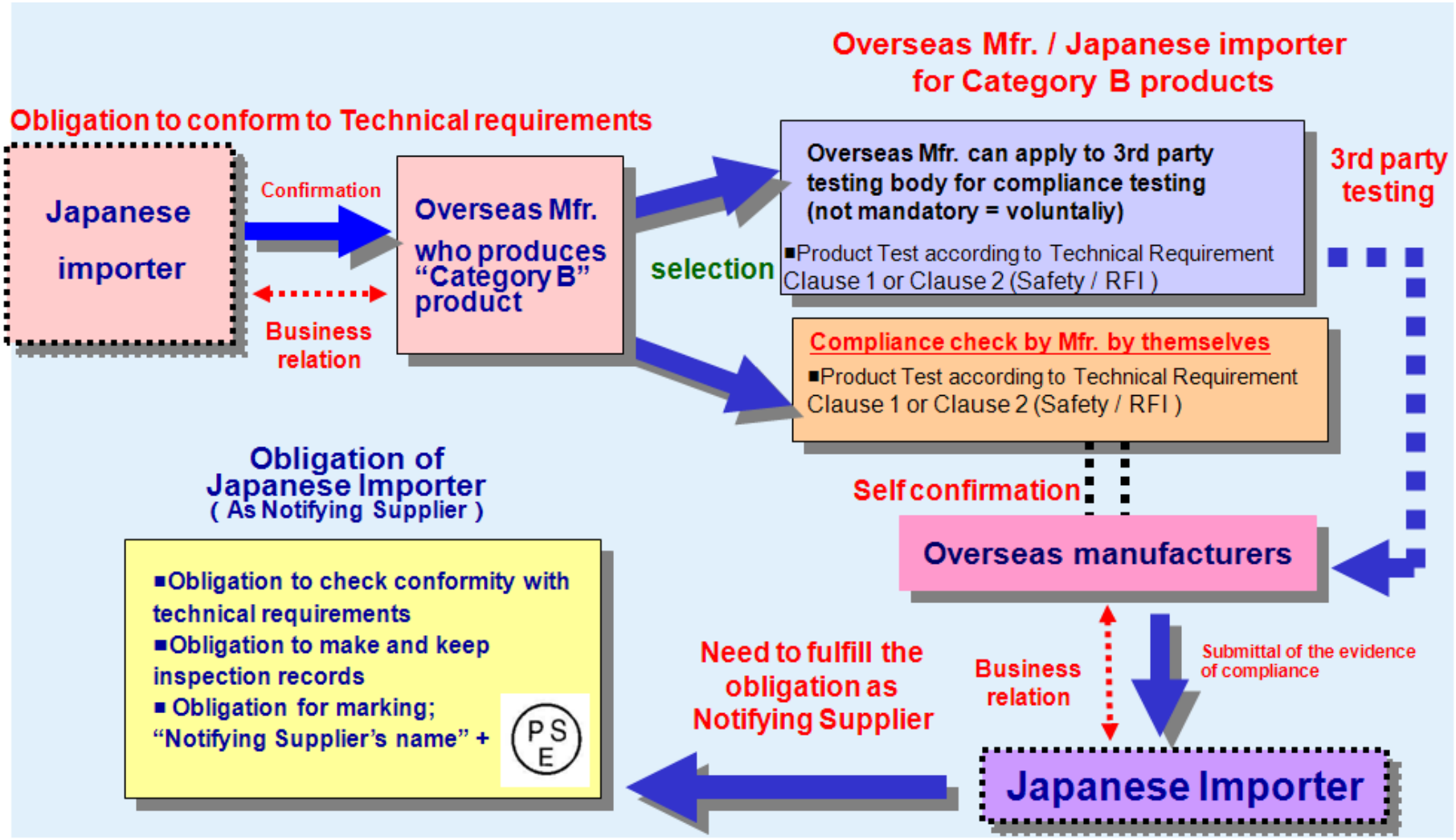
DENAN Flowchart (D)


Overseas Mfr. / Japanese importer for Category B products
Obligation to conform to Technical requirements
Japanese importer
Confirmation
Business relation
Overseas Mfr. who produces "Category B" product
selection
Overseas Mfr. can apply to 3rd party testing body for compliance testing (not mandatory = voluntaliy)
■Product Test according to Technical Requirement Clause 1 or Clause 2 (Safety / RFI)
3rd party testing
Compliance check by Mfr. by themselves
■Product Test according to Technical Requirement Clause 1 or Clause 2 (Safety / RFI)
Self confirmation
Overseas manufacturers
Obligation of Japanese Importer (As Notifying Supplier)
■Obligation to check conformity with technical requirements
■Obligation to make and keep inspection records
■ Obligation for marking; "Notifying Supplier's name" +
PSE
Need to fulfill the obligation as Notifying Supplier
Business relation
Submittal of the evidence of compliance
Japanese Importer

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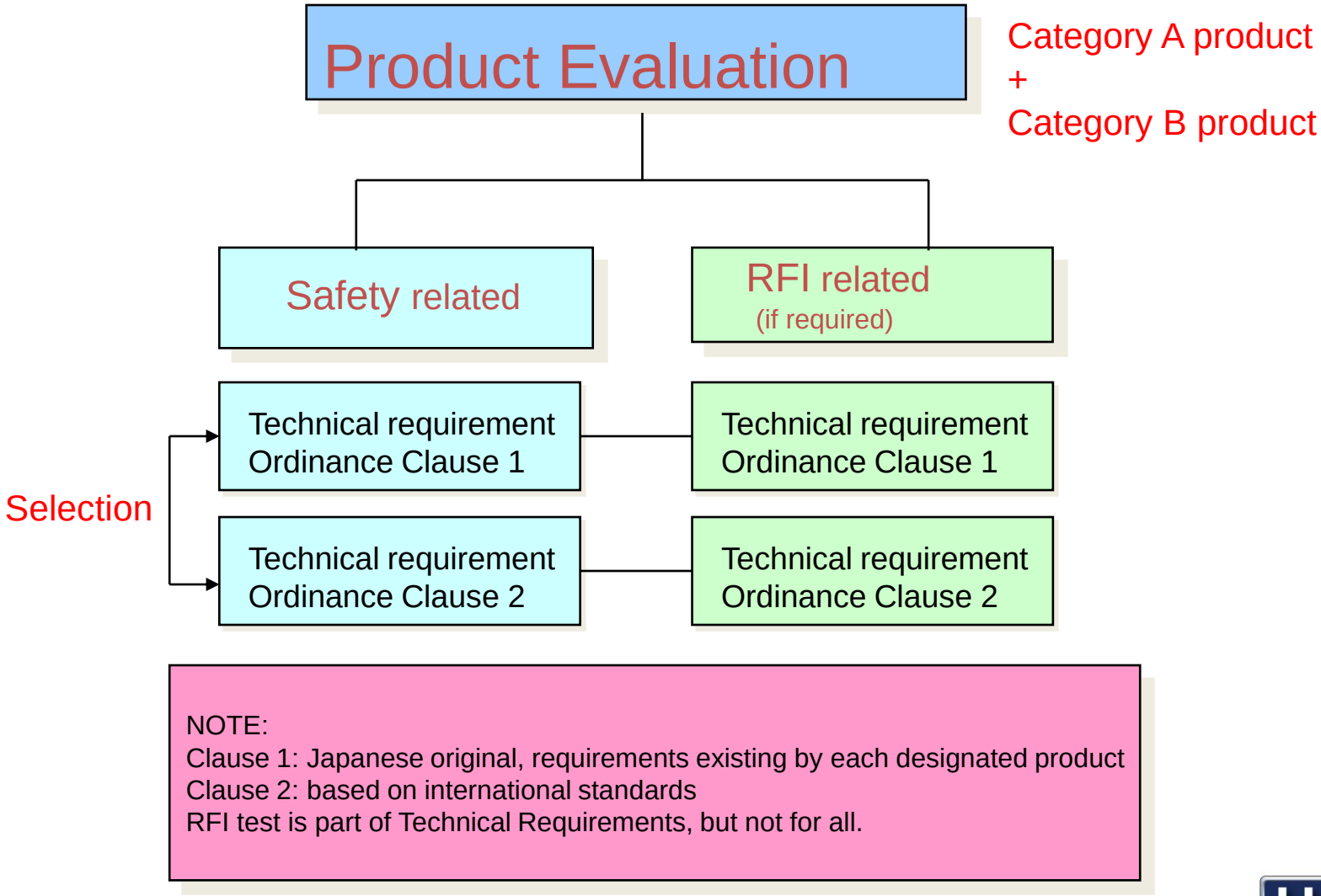
Electrical Appliance and Material Safety Law (DENAN)



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Applicable Technical Requirements / Standards

Products specified by "DENAN Law" should be tested in accordance with the technical requirements /standards specified by MITI Ordinance Clause 1 or 2

Selection Possible
(Chose one)

MITI Ordinance for Technical requirements

MITI Ordinance Clause 1

Technical requirements

Appendix 1-8

(Remarks)
Not only Safety requirements but also RFI requirements are included.

MITI Ordinance for Technical requirements

MITI Ordinance Clause 2

Technical requirements

J-IEC standards

(Remarks)
Not only Safety requirements but also RFI requirements are included.

Technical Requirements consist of two standard groups :

Category A products / Category B products are required to be tested according to the following standards.
(Either Clause 1 or Clause 2) Need to be in compliance with either Clause 1 or Clause 2.

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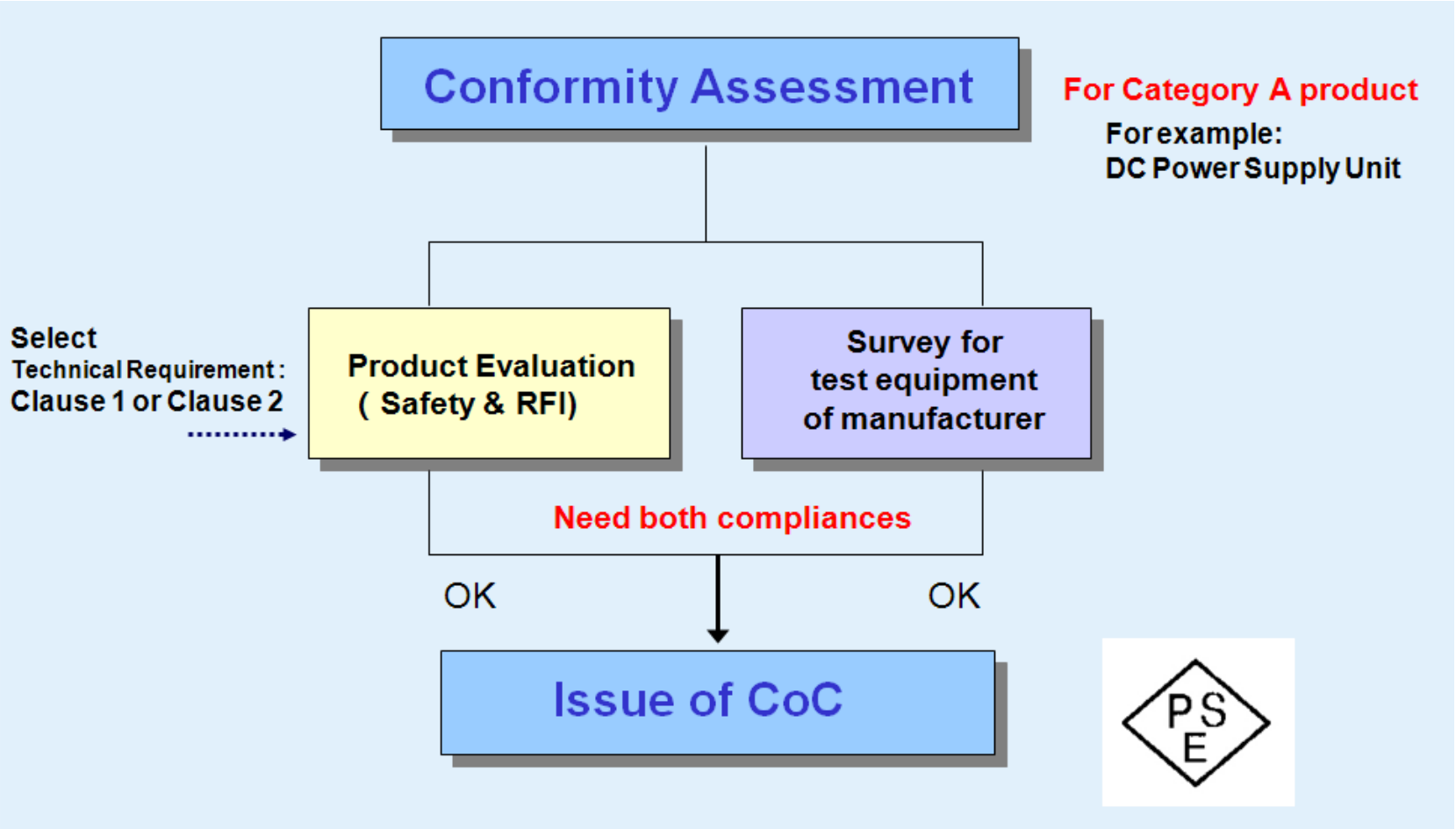
Category A product



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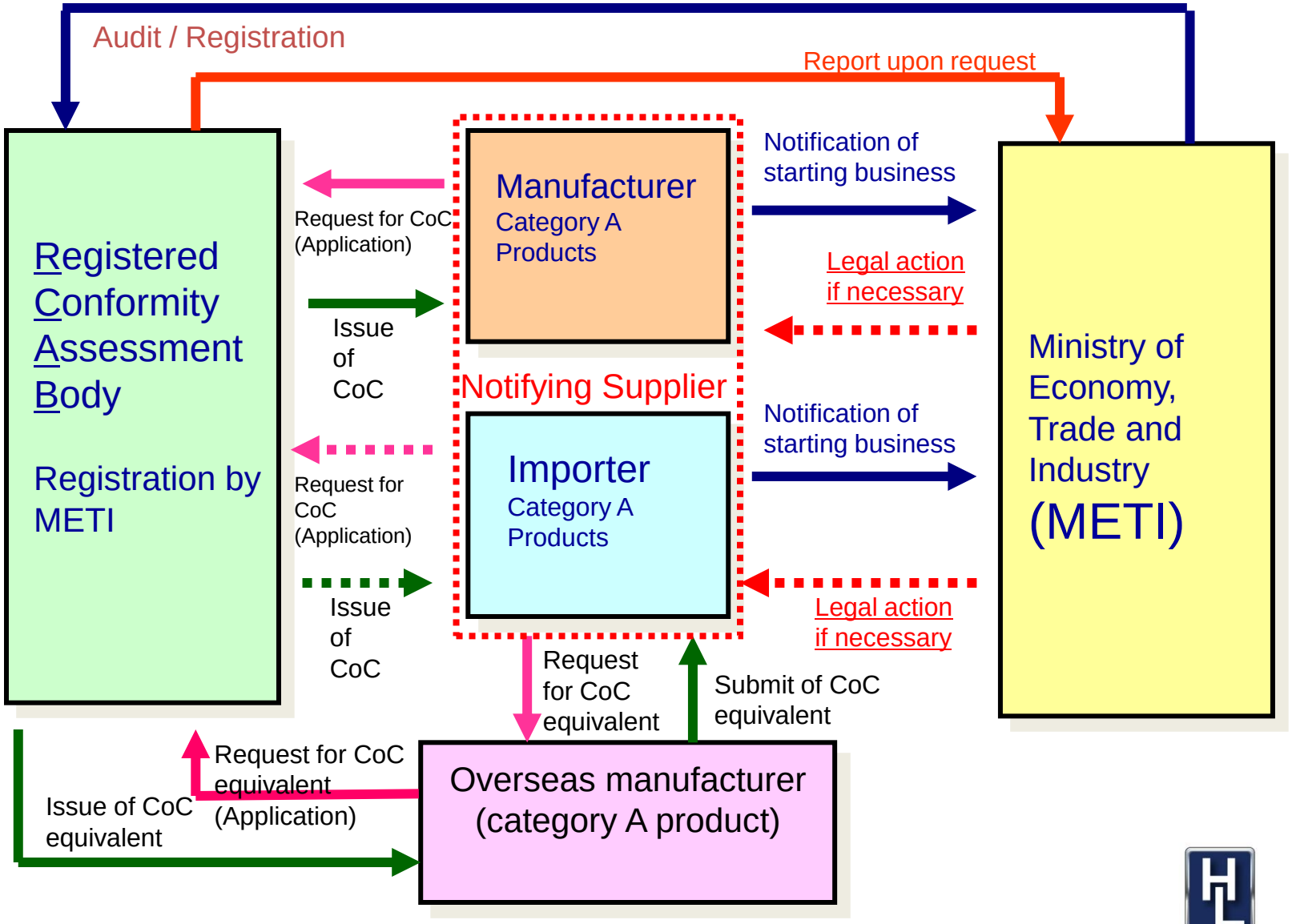
Manufacturer survey by RACB



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New Pharmaceutical Affairs Law (PAL)

薬	*Yaku* Medicine	Pharmaceutical
事	*Ji* issue, topic	Affairs
法	*Hō* law	Law

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Pharmaceutical Affairs Law (PAL, 'Yakujihō')

厚生労働省
Ministry of Health, Labour and Welfare

http://www.mhlw.go.jp/

Article 1:
This law is intended to provide regulations required to ensure the quality, efficacy and safety of drugs, quasi-drugs, cosmetics and medical devices and to improve the public health and hygiene through necessary measures taken to promote the research and development of drugs and medical devices which are of particular importance to the medical practice.

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New System of Medical Devices Classification

General Medical Devices – Class I, extremely low risk

Potential risk is almost insignificant in case of malfunction or side effect.
Examples: scalpel, X-Ray film

(Designated) Controlled Medical Devices – Class II, low risk

Having potential risk in case of malfunction or side effect.
Examples: MRI, electronic sphygmomanometers, gastric catheters

Specially Controlled Medical Devices – Class III / IV, middle/high risk

Potential risk is significant in case of malfunction or side effect.
Examples: dialyzer, pacemaker, stent

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Product Certification

Classification by PAL			
Class I	Class II	Class III	Class IV
General MD	(Designated) Controlled MD	Specially Controlled MD	

	Product Certification	Product Approval
no requirements	by RCB	by MHLW (Application to PMDA)

- RCB: Registered Certification Body

  (Designated) Controlled MD: Designated with certine criteria by MHLW

- PMDA: Pharmaceuticals and Medical Devices Agency (Independent Agency of the MHLW)

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Marketing Authorization Holder (MAH)

Resposible for distribution, quality of the product and manufacturing, and for vigillance system

Products can be sold only to MAH(er) ☺ or Manufacturer

License for Marketing Authorization Holders (Article 12)

Classification by PAL			
Class I	Class II	Class III	Class IV
General MD	Designated Controlled MD	Specially Controlled MD	

Type of Marketing Authorization Holders		
No. 3 Type	No. 2 Type	No. 1 Type License for Marketing Business of Medical Devices

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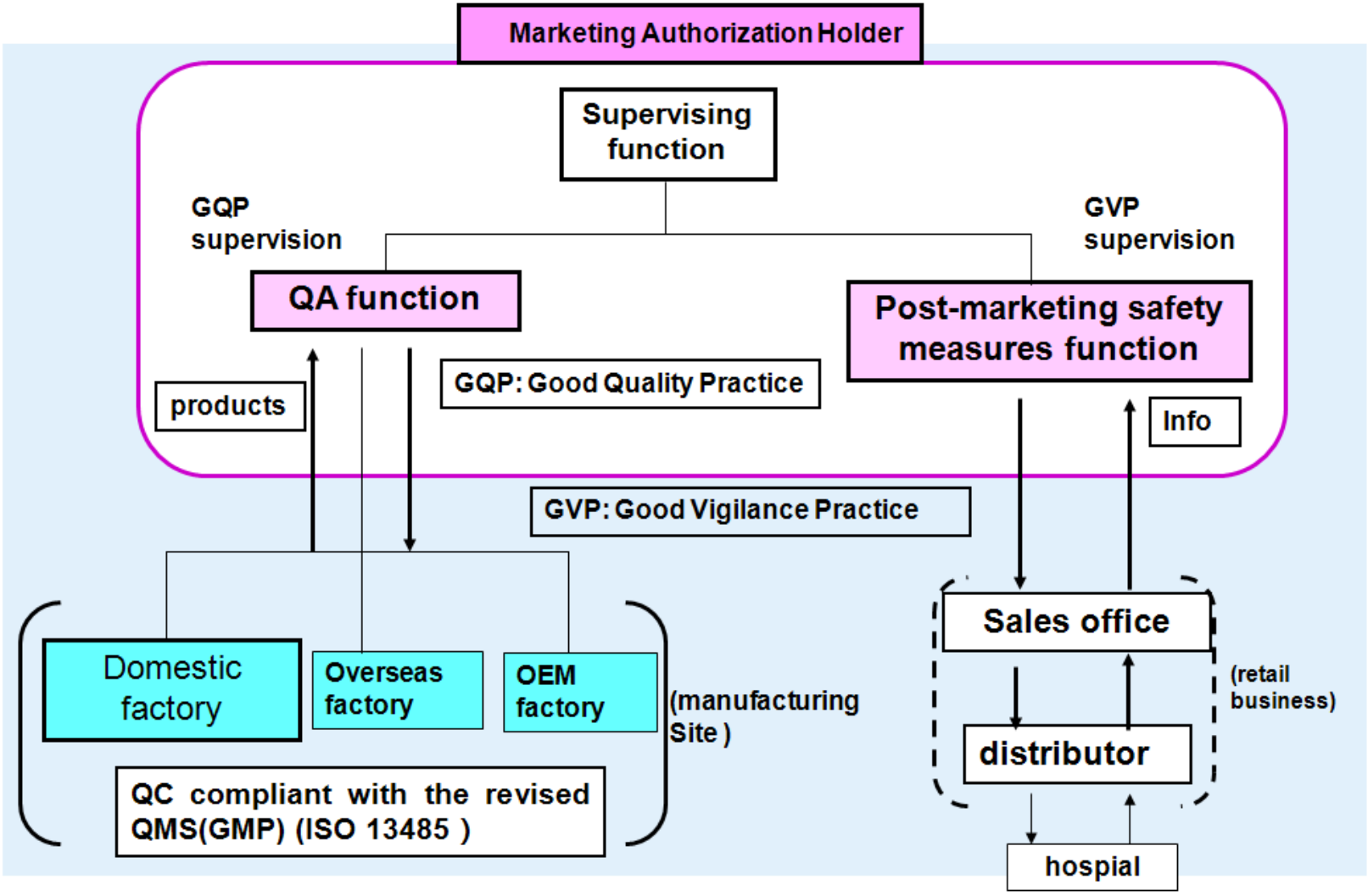

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Marketing Authorization System

1. ‘License to Marketing Business’ → MAH
   Marketing Authorization Holder

2. ‘License (Registration) for Manufacture‘
   Production License (-Registration)

3. ‘Device Approval (MHLW) / Certification (RCB)‘
   Product Approval / Certification

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Special Rules for Foreign Manufacturers

A foreign manufacturer who intends to get product approval or product certificate needs Appointed/Designated MAH (D-MAH) in Japan

D-MAHer may be:

(1) Distributor

(2) Third party

(3) Company's subsidiary in Japan

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License (Registration) for Manufacture

'License for Manufacture' is required for all production sites (also abroad, with the exception of component suppliers).

Inspection and registration is done by Prefecture and PMDA (Pharmaceuticals and Medical Devices Agency). These organizations reserve the right to do an Inspection/Audit on-site.

Depending on the category of the license, the building and its equipment are subject to different requirements.

Manufacture license categories:

- **Type No. 1 'Animal Origin Devices' (PAL, Article 43)**
- **Type No. 2 'Sterile Devices'**
- **Type No. 3 'Other than No.1 and No.2 (Other general devices)**
- **Type No. 4 'License for Labeling, Packaging and storage**

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Accreditation of Foreign Manufacturer by PMDA

A person intending to manufacture in foreign countries drugs or medical devices etc. that are imported to Japan may be accredited by the Minister as a foreign manufacturer.

Accreditation is granted for each site according to the categories.

Accreditation shall be renewed every 5 years.

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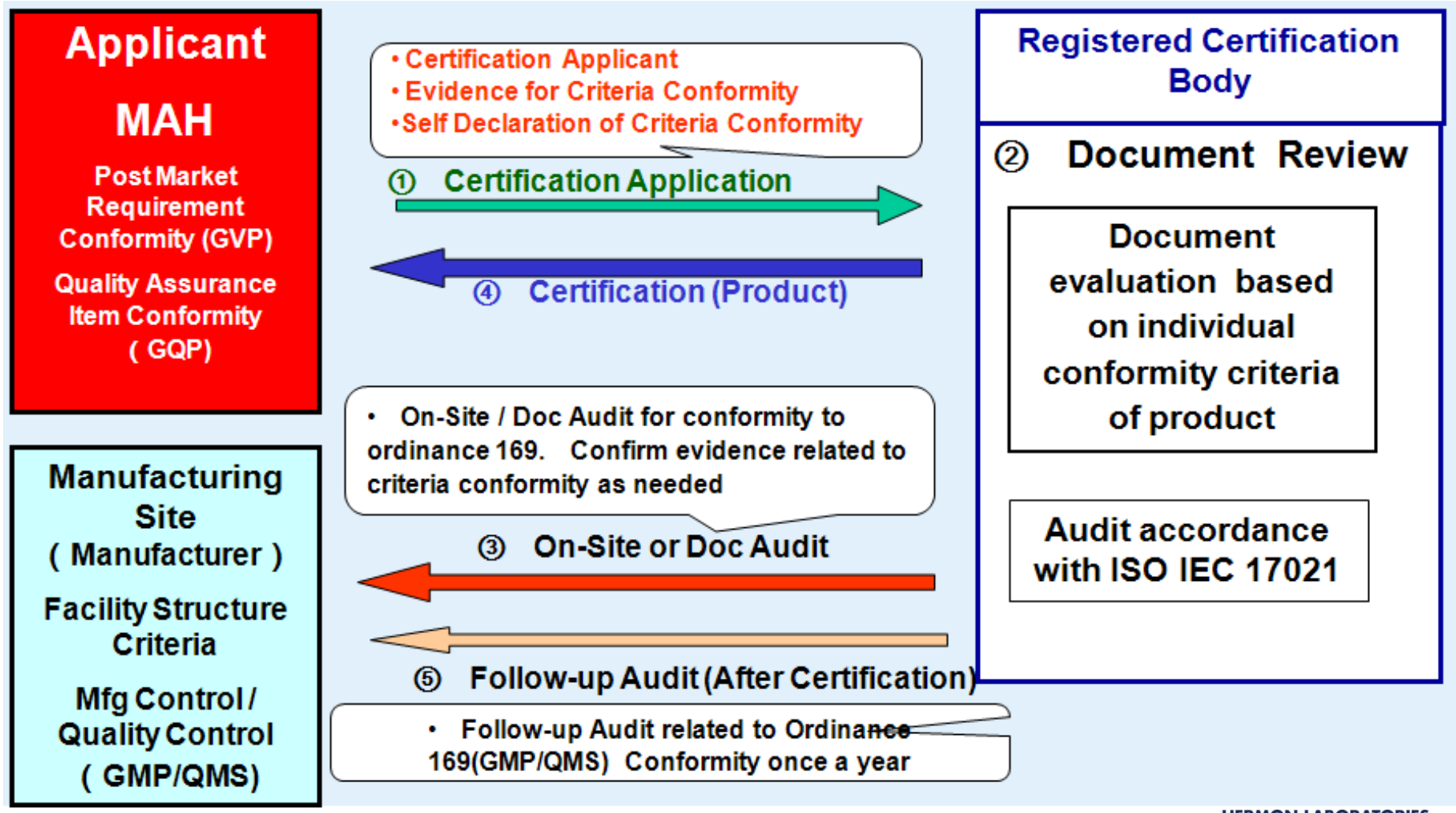
Certification Process by Third Party Certification (RCB)

Approval (Shōnin) of Medical Device by PMDA
Certification (Ninshō) of Medical Device by RCB (Registered Certification Body)


Applicant
MAH
Post Market Requirement Conformity (GVP)
Quality Assurance Item Conformity (GQP)
Manufacturing Site (Manufacturer)
Facility Structure Criteria
Mfg Control / Quality Control (GMP/QMS)
• Certification Applicant
• Evidence for Criteria Conformity
• Self Declaration of Criteria Conformity
① Certification Application
④ Certification (Product)
• On-Site / Doc Audit for conformity to ordinance 169. Confirm evidence related to criteria conformity as needed
③ On-Site or Doc Audit
⑤ Follow-up Audit (After Certification)
• Follow-up Audit related to Ordinance 169(GMP/QMS) Conformity once a year
Registered Certification Body
② Document Review
Document evaluation based on individual conformity criteria of product
Audit accordance with ISO IEC 17021

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Registration of the Production Site

Application:

- Name of the manufacturer
- Address
- Registration category
- Attachment for buildings and equipment
- Name & private address of the management representative
- Name & address of the applicant (could be foreign manufacturer or MAH)

Attachments:

- Overview/technical drawings of the buildings and the equipment
- Resume of the management representative
- List of the manufactured products
- Manufacturing process
- Copies of existing licenses, approval or certificates

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3 simple steps to access Japan

1. **Appointment of the DMAHer in Japan**
2. **Accreditation of the production facility by PMDA**
3. **Application for product approval (via DMAH or directly)**
   a) Class II: to RCB
   b) Class III, IV: to PMDA

RCB/PMDA reviews the product application documents and checks the QMS(GMP) compliance (on-site Audit or Document Review of manufacturing facilities)

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Supplemental explanation on Japanese regulations

There are a number of products applicable to DENAN and “Pharmaceutical Affairs Law”.
Examples: electric inhalators (heater or motor operated), household heating therapeutic appliances, electric massagers (motor-operated), electric bubble generators for bathtubs (motor-operated), magnetic therapeutic apparatus, household therapeutic ray apparatuses, household low frequency therapeutic apparatuses, etc.

Transformers or DC power supply units which are used only for medical equipment and which are in the range specified by DENAN, are in the scope of DENAN but the “Pharmaceutical Affairs Law” does not apply. Detachable power cords are also treated in the same manner.

Products subject to DENAN and with telecom or radio function, are also subject to the “Telecommunication Business Law” or “Radio Law” in addition to DENAN.
Examples: receivers with modem function for telecommunication and/or radio communication function such as Bluetooth.

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Q & A

Thank You!

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